

TSCA New Chemicals Program Mixed Metal Oxides (MMOs) – Cathode Active Materials (CAMs) Approach

Kick-Off Webinar #1
November 17, 2022



Agenda

- Background
- Purpose of the Webinar
- What are MMOs/CAMs?
- How are MMOs/CAMs Regulated Under TSCA section 5?
- Overview of Standardized Approach
- Determination & Potential Consent Order Terms
- Use of the TSCA Inventory & Bona Fide Process
- CAM Webinar #2 Sneak Peak
- Additional Resources



Background

- On October 5, EPA announced a new effort under the Toxic Substances Control Act (TSCA) to implement a standardized process to assess risk and apply mitigation measures, as appropriate, for mixed metal oxides (MMOs) used in new and modified cathode active materials (CAMs).
- MMOs have many electrical applications in batteries and uses as catalysts, adsorbents, and in ceramics. Notably, MMOs, including CAMs, are a key component in lithium-ion batteries used in electric vehicles, which are a growing and important industry.
- Like all chemical substances not listed on the TSCA Inventory, MMOs, including new and modified CAMs, are subject to section 5 of TSCA, which requires manufacturers (including importers) of new chemical substances to provide EPA with notice before initiating the activity by submitting a Premanufacture Notice (PMN), unless an exemption applies.
- This effort supports President Biden's agenda to tackle the climate crisis and will complement the resources flowing to EPA from legislation signed by the President.



Purpose of this Webinar

1. Ensure clarity to the regulated community about TSCA section 5 regulation of Mixed Metal Oxides (MMOs) including Cathode Active Materials (CAMs) as stated in the October 2022 Compliance Advisory
2. Provide an introduction to EPA's initiative to standardize new chemical reviews for MMOs, including CAMs
3. Ensure the regulated community understands the steps for navigating the new submission process, including in relation to the TSCA Inventory, Nomenclature, and the Bona Fide process.



Coming in Early Winter 2023 – Second Webinar

- The second webinar will:
 - Provide detail on the standardized risk assessment approach
 - Present new features – risk calculator and decision tree
 - Present various case scenarios



Statutory & Regulatory Basics

- The TSCA New Chemicals program serves a "gatekeeper" role to help manage potential risks to human health and the environment from chemicals new to the marketplace.
- TSCA section 5 requires that any person planning to manufacture (including import) a non-exempt new chemical substance (i.e., a chemical not on the TSCA Inventory) notify EPA before beginning that activity. This notice is known as a premanufacture notice (PMN).
- EPA is generally required to review these PMNs within 90 days, assess the potential risks to human health and the environment of the chemical under the conditions of use, and to make an affirmative determination.
- Where the chemical substance presents or may present an unreasonable risk, EPA must take action to prevent those risks before the chemical can enter commerce.
- Potential submitter can request EPA to confirm whether or not their chemical is already on the Inventory (i.e., Bona Fide process)



What are Mixed Metal Oxides (MMOs) and Cathode Active Materials (CAMs)? (1)

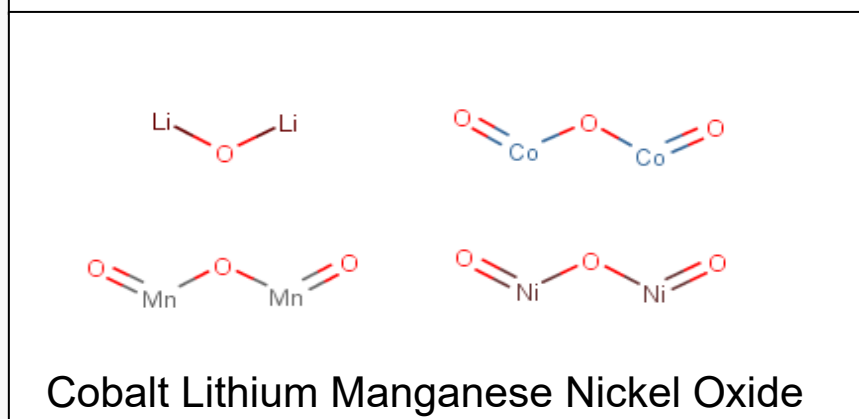
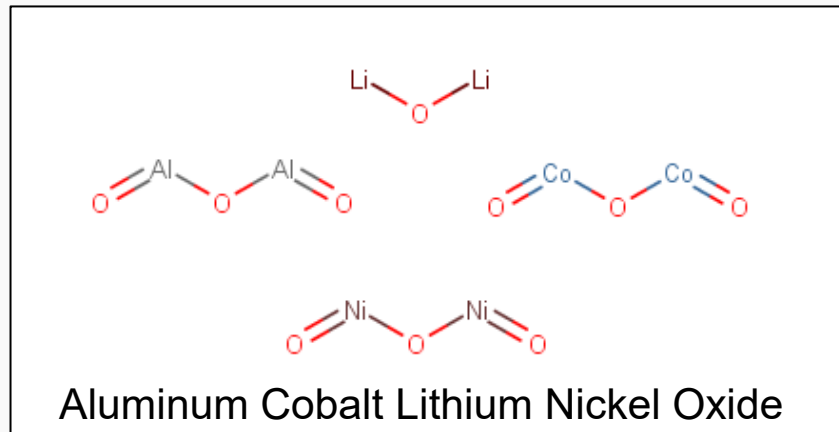
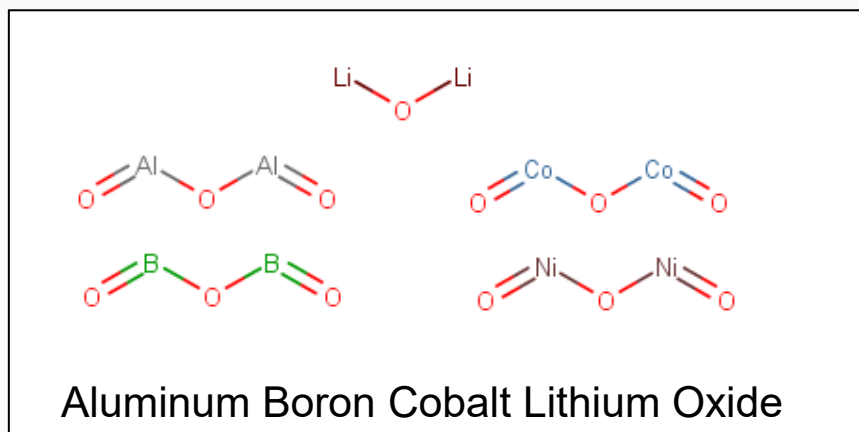
- Mixed metal oxides have numerous electrical applications in batteries, including lithium-ion batteries used in electric vehicles and renewable energy storage, sensors, biosensors, superconductors, semiconductors as well as use as catalysts, adsorbents, and in ceramics.
- A critical component of battery technology is the raw material that makes up the cathode of the battery, called the CAM. As a chemical raw material, a CAM must be compliant with TSCA to be commercially manufactured (including imported) in the United States and processed for purposes of creating the cathode component of a battery.



What are Mixed Metal Oxides (MMOs) and Cathode Active Materials (CAMs)? (2)

- CAMs are metal oxides, typically including lithium, nickel, cobalt, and other additional modifier metal oxides, and are the key material used in the production of the cathode in battery cells which are subsequently assembled into a battery.
- Modified CAMs include small amounts of certain metals (often called dopants by the industry) such as aluminum, boron, tungsten, titanium, magnesium, zirconium, or niobium oxide to improve performance.

Example MMOs





How are MMOs/CAMs Regulated Under TSCA Section 5?

- EPA recently received stakeholder inquiries as to whether modified CAMs, which are mixed metal oxides, are subject to the TSCA section 5 new chemical requirements or exempt from notification requirements per 40 CFR 720.30(b) or (h)(7).
- On October 5, 2022, EPA issued a compliance advisory to affirm that CAMs and modified CAMs that are not on the TSCA Inventory are chemical substances subject to TSCA new chemical requirements and have been subject to such requirements since 1976.
- EPA also reaffirmed that modified CAMs are not considered mixtures and are chemical substances subject to TSCA (see next slide).



Modified CAMs Are Not Considered Mixtures

- As a general matter, modified CAMs are not considered mixtures that would be generally exempt from Premanufacture Notice (PMN) requirements.
- EPA has responded to similar inquiries regarding mixed metal oxides and activated phosphors in which stakeholders argued those substances are mixtures and thus should be exempt from the TSCA section 5 new chemical notification requirements.
- EPA rejected those arguments. EPA has reviewed hundreds of TSCA section 5 submissions for mixed metal oxides, including CAMs and modified CAMs under the TSCA new chemicals program since the 1980s, many of which were subsequently listed on the TSCA Inventory.
- This indicates that it is already widely understood within industry that the potentially unlimited number of intentionally generated metal oxide substances that could be synthesized from a particular set of atoms are not all equivalent to a single mixture of simple, individual metal oxides.
- EPA believes it has consistently administered this approach throughout the implementation of TSCA. In certain individual cases, an exemption from PMN reporting requirements may be available. Exemptions from PMN reporting requirements are detailed at 40 CFR 720.30, 720.36, 720.38, and in 40 CFR Part 11723.



Modified CAMs Do Not Qualify for Exemption Under 40 CFR 720.30(h)(7)

- EPA has long interpreted this exemption as limited to a chemical substance that:
 - is formed from a chemical reaction that involves the use of a chemical substance of the type described in 40 CFR 720.30(h)(7);
 - does not function to provide one or more primary properties that would determine the use of the product or product mixture distributed in commerce; and
 - is not itself the one intended for distribution in commerce as a chemical substance per se (although it may be a component of the product, product mixture, or formulation, it has no commercial purpose separate from the product, product mixture, or formulation of which it is a part).
- With respect to a modified CAM, dopants are intentionally added to a base CAM to become part of the base CAM, resulting in the modified CAM.
- The modified CAM therefore is not formed incidentally and is the chemical substance that is manufactured for distribution in commerce in its own right, as a chemical substance per se.



October 2022 Compliance Advisory

COMPLIANCE ADVISORY October 2022

Applicability of the Toxic Substances Control Act to Mixed Metal Oxides, which include Cathode Active Materials (CAMs) and Modified CAMs

EPA Website link: https://www.epa.gov/system/files/documents/2022-10/CAMs%20and%20modified%20CAMs%20Compliance%20Advisory_10-5-22.pdf

Purpose: EPA is reaffirming in this Compliance Advisory that mixed metal oxides, which include Cathode Active Materials (CAMs) and modified CAMs, are chemical substances subject to the Toxic Substances Control Act (TSCA). Anyone who plans to manufacture (including import) a mixed metal oxide, including a CAM or modified CAM, that is not on the TSCA Inventory must comply with the TSCA section 5 new chemical requirements and implementing regulations. EPA is also reaffirming that modified CAMs are not considered mixtures and are chemical substances subject to TSCA.

Why is EPA issuing an advisory now?

EPA has recently received stakeholder inquiries as to whether modified CAMs, composed of mixed metal oxides, are subject to the TSCA section 5 new chemical requirements or exempt from notification requirements per 40 CFR 720.30(b) or (h)(7). EPA is issuing this advisory to affirm that CAMs and modified CAMs that are not on the TSCA Inventory are chemical substances subject to TSCA new chemical requirements and have been subject to such requirements since 1976.

What are Mixed Metal Oxides, including Cathode Active Materials (CAMs) and modified CAMs?

Mixed metal oxides have numerous electrical applications in batteries, including lithium-ion batteries used in electric vehicles and renewable energy storage, sensors, biosensors, superconductors, semiconductors as well as use as catalysts, adsorbents, and in ceramics.

A critical component of battery technology is the raw material that makes up the cathode of the battery, called the CAM. As a chemical raw material, a CAM must be compliant with TSCA to be commercially manufactured (including imported) in the United States and processed for purposes of creating the cathode component of a battery.

CAMs are metal oxides, typically including lithium, nickel, cobalt, and other additional modifier metal oxides, and are the key material used in the production of the cathode in battery cells which are subsequently assembled into a battery.

Modified CAMs include small amounts of certain metals (often called dopants by the industry) such as aluminum, boron, tungsten, titanium, magnesium, zirconium, or niobium oxide to improve performance.

What are the TSCA section 5 new chemical requirements?

Section 5 of TSCA requires anyone who plans to manufacture (including import) a new chemical substance for a non-exempt commercial purpose to provide EPA with notice before initiating the

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EPA Website link:

https://www.epa.gov/system/files/documents/2022-10/CAMs%20and%20modified%20CAMs%20Compliance%20Advisory_10-5-22.pdf



Overview of Standardized MMOs/CAMs Approach

- Amenable to standardized approach and allows multiple submissions to be processed consistently
- Supports sectors important to fighting the climate crisis, like electric battery manufacture
- Allows for more consistent science and risk management



Determinations & Requisite Actions for PMNs (1)

Presents an Unreasonable Risk

*Section 5(f) order or section 6(a) Rule: Restriction /prohibition of manufacturing, processing, or distribution or disposal

Not Likely to present an unreasonable risk

*May commence manufacture after the determination is made
*Section 5(g): Statement in the Federal Register

Information is insufficient to permit a reasoned evaluation of the risk

*Section 5(e) order: regulation pending development of more information

Insufficient information to permit a reasoned evaluation & **may present** unreasonable risk

*Section 5(e) order: regulation pending development of more information

Produced in **substantial quantities** and may reasonably be anticipated to enter the environment in substantial quantities or there may be significant or substantial human exposure

*Section 5(e) order



Determinations & Requisite Actions for PMNs (2)

- For a new chemical, any of the five determinations are possible depending on the review of the notice
- Historically, after the risk assessment is complete, the determination made for new chemical MMOs has often been “...Insufficient information to permit a reasoned evaluation & **may present** an unreasonable risk”



Determinations & Requisite Actions for PMNs (3)

“...Insufficient information to permit a reasoned evaluation & **may present** an unreasonable risk”

- In the absence of sufficient information to permit the Administrator to make a reasoned evaluation of the health and environmental effects of the chemical substance, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to human health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator. TSCA § 5(a)(3)(B)(ii)(I).



Outcomes of a “May Present” Finding

- Upon a “may present” finding, the Administrator shall take the actions required under section 5(e)
 - Regulation under section 5(e): Regulation Pending the Development of Information
 - Section 5(e) order - Typically a consent order
 - Commercialization with restrictions
 - Testing, if required, is generally due at a specified point after commercialization of the chemical substance, unless risks cannot be mitigated then testing needed before commercialization of the chemical substance



Potential Consent Order Terms for MMOs Under Standardized Process (1)

- Manufacturing/Processing/Use:
 - No domestic manufacture
 - Manufacture in an enclosed process
 - Manufacture in a form that is not respirable
 - May not manufacture in any manner that results in inhalation exposure
- Disposal:
 - Disposal by landfill or metal reclamation
 - There also may be restrictions on air releases as appropriate
 - There may be release to water restriction



Potential Consent Order Terms for MMOs Under Standardized Process (2)

- Worker Protection:
 - Dermal personal protective equipment
 - Respiratory personal protective – at least an APF of 50 and usually an APF of 1000
 - There may also be dust/engineering controls and use of a NCEL if needed
- Hazard Communication:
 - Hazard Statements



Importance of TSCA Inventory for MMOs: Purpose

- Required by TSCA section 8(b)
 - Comprised of individual chemical substances that are manufactured or processed in the United States.
 - Chemical substance is defined under TSCA section 3(2)(A).
- Central to TSCA
 - Is the basis for determining whether a chemical substance is a new or existing chemical substance under TSCA.
 - Provides information where existing chemicals are subject to manufacturing or use restrictions.
 - Substances not listed on the Inventory may be subject to new chemical reporting under TSCA section 5.
 - Substances listed on the Inventory may be subject to existing chemical reporting under other sections of TSCA.



Importance of TSCA Inventory for MMOs: Nomenclature

TSCA Inventory Listings

- Are for individual chemical substances and are named according to Chemical Abstracts Service (CAS) nomenclature rules

Types of Chemical Substances

- Class 1 substance
- Class 2 substance
- UVCB [Chemical substances of **U**nknown or **V**ariable composition, **C**omplex reaction products, and **B**iological materials]



CAMs on the TSCA Inventory

- For example, the following are on the non-confidential portion of the TSCA Inventory:
 - Cobalt lithium manganese nickel oxide (CASRN 182442-95-1)
 - Lithium nickel oxide (CASRN 12031-65-1)
 - Aluminum cobalt lithium nickel oxide (CASRN 177997-13-6)
 - Aluminum boron cobalt lithium nickel oxide (CASRN 207803-51-8)



Bona Fide Notices (1)

40 CFR 720.25 - Determining Whether a Chemical Substance is on the TSCA Inventory

- (b)(1) “... A person who intends to manufacture (including import) a chemical substance not listed by specific chemical name in the public portion of the Inventory may ask EPA whether the substance is included in the confidential Inventory. EPA will answer such an inquiry only if EPA determines that the person has a bona fide intent to manufacture (including import) the chemical substance for commercial purposes.”
- (b)(2) A bona fide notice must be submitted via CDX using the e-PMN software. [See § 720.40(a)(2)(ii) for how to access the software.]



Bona Fide Notices (2)

40 CFR 720.25(b)(5)-(7) – EPA Search and Determination

- If a bona fide intent is confirmed, and if the bona fide notice includes sufficient information such that EPA can make a conclusive determination of the TSCA Inventory status of a substance, EPA will search the full TSCA Inventory, including confidential listings, and inform the bona fide notice submitter of the TSCA Inventory status of the substance.
- For a substance determined to be a confidential listing on the Inventory, a disclosure of the confidential chemical identity to a person with a bona fide intent to manufacture (including import) the substance is not considered a public disclosure of confidential business information under TSCA section 14.



Webinar #2: Sneak Peak Early Winter 2023

- Details of standardized risk assessment for MMOs/CAMs
- Share new features – risk calculator and decision tree
- Provide hands-on training using case studies



Additional Resources

- Points of Contact

- Inventory (Tracy Williamson – Williamson.tracy@epa.gov)
- Risk Assessment (Keith Salazar – Salazar.Keith@epa.gov)
- Risk Management (Jim Alwood – Alwood.jim@epa.gov)

- Additional Information

- [Standardized Approach for Mixed Metal Oxides New Chemicals Review Training/Outreach](#)
- TSCA [Compliance Advisory](#) issued in October 2022
- [New Chemicals Review Process](#) under TSCA
- TSCA [Inventory](#) and [Bona Fide Process](#) (40 CFR 720.25)
- Applicable Regulations for [Premanufacture Notice](#) (40 CFR 720) and [Significant New Use Notice and Rules](#) (40 CFR 721)
- [EPA's "Points to Consider When Preparing TSCA New Chemical Notifications"](#)
- [Information about Filing a Premanufacture Notice](#)