

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

activity (see 40 CFR Part 720). Any substance that is not on the TSCA Inventory is a new chemical substance under section 5(a)(1)(A) of TSCA. Prior to manufacture (including import) of a new chemical substance for commercial purposes, a notice, called a Premanufacture Notice (PMN), must be filed with EPA under section 5 of TSCA, unless an exemption applies.

What is the TSCA Inventory?

The TSCA Inventory is a list of chemical substances manufactured (including imported) or processed in the United States that do not qualify for an exemption or exclusion under TSCA. Section 8(b) of TSCA requires EPA to compile, keep current, and publish this list of chemical substances. Also called “the Inventory,” it plays a central role in the regulation of most industrial chemicals in the United States. The Inventory was initially published in 1979, and a second version, containing about 62,000 chemical substances, was published in 1982. The TSCA Inventory has continued to grow as new chemicals are added after notice reviews are completed and a Notice of Commencement is received. The Inventory now has more than 86,000 chemicals. Information on the TSCA Inventory can be located on EPA’s public website at <https://www.epa.gov/tsca-inventory>.

Can modified CAMs be considered mixtures and therefore exempt from new chemical substance notification requirements under Section 5 of TSCA?

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 for reasons explained below. 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 723.

Do modified CAMs qualify for exemption under 40 CFR 720.30(h)(7)?

No. The exemption at 40 CFR 720.30(h)(7) does not apply to modified CAMs. EPA has long interpreted this exemption as limited to a chemical substance that: (1) 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); (2) 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 (3) 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.

Has EPA assessed mixed metal oxides, including CAMs and modified CAMs?

Yes. 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.

Are there CAMs and modified CAMs listed on the TSCA Inventory?

Yes. 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)

How can you be certain if your mixed metal oxide, including a CAM or modified CAM, is listed on the TSCA Inventory?

If a person with a valid commercial intent to manufacture or import a mixed metal oxide, including a CAM or modified CAM is uncertain if their chemical substance is listed on the TSCA Inventory, they can [submit a Bona Fide Intent to Manufacture or Import Notice \(“bona fide notice”\)](#). For more information, see 40 CFR 720.25. EPA will consider the information submitted in a bona fide notice and will provide a determination on the TSCA Inventory status for the chemical substance. In response to a bona fide notice, EPA will also inform the person if the substance is subject to regulation under TSCA section 5, including if the substance is subject to a Significant New Use Rule (SNUR) under 40 CFR Part 721.

What is a SNUR?

TSCA Section 5(a) Significant New Use Rules (SNURs) require notice to EPA before chemical substances and mixtures are manufactured or processed for a significant new use. TSCA section 5(a) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture (including import) or process the chemical substance for that use. Information on how to submit a SNUN can be located at EPA’s public website at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-significant-new-use-notice>. Information on SNURs can be located in EPA’s regulations at 40 CFR Part 721 and EPA’s public website at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/recent-activities-new-chemicals>.

Can you manufacture or import a mixed metal oxide, including a CAM or modified CAM, if it is not listed on the TSCA Inventory?

No, unless an exemption applies. Anyone who intends to manufacture (including import) a new chemical substance that is subject to TSCA for a non-exempt commercial purpose is required to

submit a PMN at least 90 days prior to the manufacture of the substance. Manufacturers (including importers) are in violation of TSCA if they fail to comply or are late in complying with TSCA notice requirements. If you are required to submit a PMN, failure to do so is a violation of TSCA Section 15 and you may be subject to penalties. PMN submissions must include all available data, pursuant to 40 CFR 720.45 and 720.50. TSCA requires EPA to review the notice, make a determination, and, if appropriate, regulate the proposed activity to the extent necessary to protect against identified unreasonable risk of injury to health or the environment.

How are chemical substances added to the Inventory?

Following EPA's review and determination regarding a PMN, the company must provide a Notice of Commencement of Manufacture or Import (NOC, EPA Form 7710-56) to EPA on or within 30 calendar days after the date the new chemical substance is first manufactured or imported for nonexempt commercial purposes. Once a complete NOC is received by EPA, the reported substance is considered to be on the TSCA Inventory and becomes an existing chemical substance. See 40 CFR 720.102. Information on how to file a NOC can be located on EPA's website at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-pre-manufacture-notice-epa>

Disclaimer: This Compliance Advisory addresses select provisions of EPA regulatory requirements using plain language. Nothing in this Compliance Advisory is meant to replace or revise any EPA regulatory provision, or any other part of the Code of Federal Regulations, the Federal Register, or TSCA.