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EPA Holds First Webinar on Approach for Reviewing MMOs, Including New and Modified CAMs

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Government Regulation

On November 17, 2022, the U.S. Environmental Protection Agency (EPA) held the first of a two-part webinar series on EPA's new standardized process to assess risk and apply mitigation measures, as appropriate, for mixed metal oxides (MMO), including new and modified cathode active materials (CAM). Under the Toxic Substances Control Act (TSCA), EPA reviews new chemical substances before they enter the marketplace to ensure they do not present unreasonable risk to human health or the environment. In October 2022, EPA announced an "innovative effort" to help make its review of new MMOs, including new and modified CAMs, more efficient. More information on the initiative is available in our October 11, 2022, memorandum.

The webinar slides state that the purpose of the webinar was to:

- Ensure clarity to the regulated community about TSCA Section 5 regulation of MMOs, including CAMs, as stated in the October 2022 compliance advisory;
- Provide an introduction to EPA's initiative to standardize new chemical reviews for MMOs, including CAMs; and
- 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.

The second webinar, currently targeted for **early winter 2023**, will go into greater detail on the standardized risk assessment approach; present new features, including a risk calculator and decision tree; and present various case scenarios.

According to EPA's slides, MMOs have numerous electrical applications in batteries, including lithium-ion batteries used in electric vehicles and renewable energy storage, sensors, biosensors, superconductors, and semiconductors, as well as use as catalysts, adsorbents, and in ceramics. The slides note that a critical component of battery technology is the raw material that makes up the cathode of the battery, called the CAM. The slides state that 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."

EPA issued the October 2022 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. According to the slides, EPA has reviewed "hundreds" of TSCA Section 5 submissions for MMOs, including CAMs and modified CAMs, under the TSCA New Chemicals Program since the 1980s, many of which were subsequently listed on the TSCA Inventory. The slides state that 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."

According to the slides, EPA has "long interpreted" the exemption under 40 C.F.R. Section 720.30(h)(7) (the "h7 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 C.F.R. Section 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).

The slides state that 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."

EPA determined that MMOs/CAMs are amenable to a standardized approach, allowing multiple submissions to be processed consistently. For a new chemical, EPA must make one of five determinations depending on its review of the notice. According to EPA, the determination that has historically been made for new chemical MMOs has often been that there is "[i?]nsufficient information to permit a reasoned evaluation & may present an unreasonable risk." Upon a "may present" finding, EPA will take action under TSCA Section 5(e). Actions may include:

- A TSCA Section 5(e) order -- typically a consent order;
- Commercialization allowed with restrictions; and
- Testing. If required, testing is generally due at a specified point after commercialization of the chemical substance. If risks cannot be mitigated, then testing is required before commercialization of the chemical substance.

The slides list the following potential consent order terms for MMOs under the standardized process:

- Manufacturing/Processing/Use:
    - No domestic manufacture;
    - Manufacture in an enclosed process;
    - Manufacture in a form that is not respirable; and
    - 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; and
    - There may be a release to water restriction;
- Worker Protection:
    - Dermal personal protective equipment (PPE);
    - Respiratory PPE -- At least an assigned protection factor (APF) of 50 and usually an APF of 1,000; and
    - There may also be dust/engineering controls and use of a new chemical exposure limit (NCEL) if needed;
- Hazard Communication:
    - Hazard statements.

The webinar included a review of the importance of the TSCA Inventory for MMOs. If an MMO is listed on the TSCA Inventory, then a premanufacture notice (PMN) is not necessary. Because approximately a fifth of all chemicals on the TSCA Inventory are claimed as confidential business information (CBI), companies may need to submit a bona fide notice to determine if their MMOs are new chemicals.

During the question and answer portion of the webinar, EPA was asked what information a company should ask its supplier to make sure that the supplier understands the TSCA requirements. Jim Alwood, EPA, responded that a company should ask the supplier what the chemical is, what is its identity, and whether it is on the TSCA Inventory. If the supplier responds that it is a mixture of metals, then it is up to the company how to respond. Alwood suggested that if a company has questions, it should contact EPA. A participant asked for details regarding concerns that would lead to water restrictions in a consent order. Alwood stated that the restrictions depend on what data are available. Another participant asked if EPA will build specific databases. Keith Salazar, EPA, stated that EPA does not intend to build specific databases. A lot of information is already available on these metals, it is just a matter of gathering the data into one place so that there is a standardized approach. Details on this will be the focus of the next webinar. Salazar noted that the new decision

tree will not apply to nano-sized MMOs, and information about why will be provided in the second webinar.

Commentary

In this webinar, the first in a series about EPA's approach to CAMs and other MMOs, EPA focuses on its interpretation of its mixture guidance (Products Containing Two or More Substances: Formulated and Statutory Mixtures), in particular, EPA's interpretation of Section III.B., its Statutory Mixture Guidance (SMG). Manufacturers and EPA have engaged for decades in discussions about the MMO section of EPA's SMG. Over the years, EPA has taken action (*e.g.*, its notification about activated phosphors in 2010 (75 Fed. Reg. 8266)) and allowed manufacturers to submit PMNs for phosphors that were manufactured under the SMG without seeking penalty, EPA has not done so for other MMOs. EPA has issued numerous statements, including its statement in October 2022 that it does not view MMOs as statutory mixtures despite the fact that there is a section of the SMG that specifically discusses MMOs as being a type of product that may be considered a statutory mixture (*see* Example 10 of the SMG). EPA has repeatedly, and does so again in this webinar, pointed to the fact that manufacturers have submitted PMNs for MMOs over the years as conclusive evidence that MMOs are not mixtures. One manufacturer's commercial choice to not avail itself of an exemption does not eliminate another manufacturer's ability to rely upon that same exemption.

As is well established, suppliers and customers often prefer to have exempt substances (*e.g.*, exempt polymers) listed on the TSCA Inventory for their own commercial reasons, rather than relying on the applicable exemption and electing to submit PMNs. Just because one manufacturer lists an exempt polymer on the Inventory does not negate another's ability to rely upon the polymer exemption. In our view, the same is true for substances that meet the statutory mixture criteria.

There is no doubt that a reaction occurs during the manufacture of MMOs, as acknowledged in the SMG. The point of the SMG is that there are certain cases in which a manufacturer may consider the resulting product a mixture *despite the fact* that a reaction occurs and not because of it. EPA has never rescinded that guidance, it has only narrowed it with its notification about activated phosphors. EPA may prefer to rescind entirely its SMG and can formally elect to do so, but it must do so in an orderly way and allow for manufacturers that have relied on that guidance in good faith for decades time to prepare and submit PMNs, as EPA did for activated phosphors.

EPA also notes that the "h7 exemption" does not apply to MMOs, including CAMs. We agree with this interpretation. The reaction that occurs to form the MMO is not a result of the product "acting as intended" during its use.

The remainder of the webinar relates to establishing the chemical identity of CAMs, searching the Inventory, and the new chemicals process -- all of which is important information, but does not apply exclusively to MMOs in general or CAMs in particular.

Later webinars reportedly will focus on EPA's categorical approach to MMOs and CAMs. We applaud EPA taking category approaches whenever it is appropriate. EPA has used chemical categories for decades to make its review of new chemicals more efficient. That approach seemed to stall after the TSCA amendments were implemented in 2016 but has made a comeback with EPA's implementation of its categories for surfactants, cationic polymers, polymers of low solubility and low toxicity, and, more recently, biofuels, and now CAMs. We hope that EPA will continue to use its existing categories and develop additional categories in its review of new chemicals.

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