Review Report for Aluminum Oxide (CASRN 1344-28-1) Partial Exemption

May 2019: The Aluminum Association

Docket Identifier: EPA-HQ-OPPT-2019-0224

Summary of Decision: In response to a petition from the Aluminum Association[1] (hereinafter "petitioner") requesting that aluminum oxide (CASRN 1344-28-1) be added to the 40 CFR 711.6(b)(2)(iv) list of specific chemical substances for which the Environmental Protection Agency (EPA, "the Agency") has a low current interest in the processing and use information, EPA has determined that the Agency does not have a low current interest in the processing and use information collected under the Chemical Data Reporting (CDR) rule (see 40 CFR Part 711) for aluminum oxide (Al2O3). This determination is based on the totality of information available for the chemical substance, including an evaluation of all the considerations listed in 40 CFR 7l1.6(b)(2)(ii), as well as additional considerations.

Background: EPA received a petition from the Aluminum Association on January 31, 2019, requesting that aluminum oxide (Al2O3) (CASRN 1344-28-1) be added to the 40 CFR 711.6(b)(2)(iv) list of specific chemical substances that are exempt from the reporting requirements of 40 CFR 711.15(b)(4) (*i.e.*, exempt from requirements to report industrial processing and use and commercial/consumer use information). EPA has a low current interest in the substances on this "partial exemption" list and thus in the related CDR processing and use information. EPA emphasizes that low current interest is not synonymous with low hazard or low risk. As EPA stated in the preamble to the Inventory Update Reporting Amendments rule (the previous name for the Chemical Data Reporting rule), "[t]he inclusion of a chemical substance under this partial exemption is not itself a determination of the potential risks of a chemical. This partial exemption is solely intended to provide a tool to assist the Agency in better managing the collection of processing and use information under [the CDR rule]." (68 FR 848, 854, January 7, 2003). This determination is based on the Agency's interest in the chemical generally and in the processing and use information specifically: "[i]n determining whether there is low current interest in [CDR] processing and use information related to a specific chemical substance, EPA will look to the specific circumstances surrounding the chemical in question, and may use one or more of the considerations identified [in 40 CFR 711.6(b)(ii)], and/or considerations not identified [in 40 CFR 711.6(b)(ii)], to make an informed decision."[2]

The considerations used by EPA in reviewing this petition and an analysis of how those considerations relate to aluminum oxide are set forth below.

In reviewing this petition, EPA considered information submitted, as well as other information, including, but not limited to: whether the petitioned chemical substance is listed on the

[1] The Aluminum Association. "RE: Partial Exemption Request for Aluminum Oxide (CASRN 1344-28-1)". December 28, 2018. Received January 31, 2019 with attachments.

[2] As updated in 40 CFR § 711.6(b)(ii).

(A) Referred to the older reg number. And included the following: "(i.e., at least one site manufactures 300,000 pounds or more of the chemical)."

(F) ". . . adequately managed by EPA or another agency or authority."

Emergency Planning and Community Right-to-Know Act (EPCRA), Section 313 list of Toxic Chemicals and is thus reportable to the Toxics Release Inventory (TRI); 2012 and 2016 CDR submissions for the chemical substance; evaluations available through EPA's Integrated Risk Information System, the International Agency for Research on Cancer, Organisation for Economic Co-operation and Development's (OECD) High Production Volume Screening Information Data Set program, and other relevant TSCA-related programs. EPA also considered whether the substance is subject to other regulatory programs administered by EPA.

Discussion on Considerations: Petitioner references information on aluminum oxide from a variety of sources and linked it to specific considerations cited in 40 CFR 711.6(b)(2)(ii). Petitioner did not provide significant amounts of new information for EPA's consideration in this petition; rather, petitioner included their prior petition, from 2003. EPA reviewed that information, petitioner's other attachments, and publicly available sources of information. EPA's assessment of each consideration is below, with an indication of whether each consideration reflects a low current interest in this chemical and thus weighs in favor of granting or denying this petition for partial exemption.

Consideration A: Whether the chemical qualifies or has qualified in past Inventory Update Reporting (IUR) or CDR collections for the reporting of the information described in 40 CFR 711.15(b)(4).

Petitioner states that aluminum oxide (CASRN 1344-28-1) was reported to the 2012 and 2016 CDR. In their original 2003 partial exemption request letter, petitioner states that the scope of the aluminum oxide partial exemption petition is particularly for the non-fibrous forms (this is not distinguished in their January 31, 2019, letter). EPA reviewed the 2012 and 2016 CDR data for aluminum oxide and found that 134 and 176 sites, respectively, reported domestic manufacture or importation of aluminum oxide, with a nationally aggregated production volume of 8 billion to 11 billion lbs. from 2010 to 2015.

EPA has concluded that at least one manufacturing site would likely have a production volume sufficient to trigger the need to report processing and use information under the 2020 CDR (25,000 lb threshold). Thus, the petition is eligible for consideration.

Consideration B: The chemical substance's chemical and physical properties or potential for persistence, bioaccumulation, health effects, or environmental effects (considered independently or together).

Petitioner partially addresses this consideration, referencing EPA's decision to delist non-fibrous forms of aluminum oxide from Section 313 of EPCRA as available data did not demonstrate that non-fibrous forms of aluminum oxide cause significant adverse human health or environmental effects. As part of this decision, EPA stated that non-fibrous aluminum oxide was found to have weak fibrogenic potential and was not found to cause cancer or serious or irreversible pulmonary disease. Notwithstanding, EPA found this information insufficient for a decision and reviewed additional sources of data. The more recent data available for aluminum oxide and associated research indicates a concern for environmental fate. Aluminum oxide is on the OECD High Production Volume list in Canada where it has met the Categorization criteria under subsection

73(1) of the Canadian Environmental Protection Act.[3] Aluminum compounds have also been found in at least 596 of EPA's 1,699 National Priority List (NPL) sites.[4]

Human Health Effects. Aluminum oxide meets OECD/Canada's Domestic Substances List (DSL) criteria for human health concerns. Based on the available information for aluminum oxide, EPA continues to have interest in this chemical substance's potential for effects on human health, and this information thus weighs against granting the partial exemption.

Environmental Effects. Aluminum oxide meets OECD/Canada's DSL criteria for environmental concerns and is listed as inherently toxic to aquatic organisms. Based on the available information for aluminum oxide, EPA continues to have an interest in this chemical, and this information thus weighs against granting the partial exemption.

Environmental Fate. The data and associated research available for aluminum oxide indicate a concern for environmental fate. Available information from OECD/Canada's DSL categorization results indicate that aluminum oxide is persistent in the environment. These categorization results are not determinative on whether aluminum oxide is bioaccumulative or not.

The data contributing to EPA's consideration of this factor do not support a low current interest in aluminum oxide. This consideration weighs against establishing a partial exemption.

Consideration C: The information needs of EPA, other federal agencies, tribes, states, and local governments, as well as members of the public.

Petitioner characterizes to some extent the expected information needs, claiming that CDR information would not be relevant. In support of this proposition, petitioner again references EPA's decision to delist non-fibrous forms of aluminum oxide as well as citing studies from the Agency for Toxic Substances and Disease Registry (ATSDR), Environment Canada and Health Canada, and the International Programme on Chemical Safety. Though they do not address this consideration in their January 31, 2019, letter, in their 2003 letter, petitioner states that none of these agencies raised issues regarding aluminum oxide and that the substance is well studied and presents no information needs. However, researchers affiliated with NIH have identified research needs to further improve risk assessments on aluminum compounds (including aluminum oxide), specifically recommending studies on the potential for respiratory tract disease/illness and neurological effects due to occupational exposure via inhalation of aluminum and aluminum compounds.[5]

[3] OECD; Canada DSL Categorization Results. https://canadachemicals.oecd.org/Search.aspx.
[4] Agency for Toxic Substances and Disease Registry (ATSDR) (2008). Toxic Substances Portal – Aluminum. https://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=190&tid=34. Accessed April 10, 2019.
[5] U.S. National Library of Medicine; NIH. Krewski, D. et al. "Human Health Risk Assessment for Aluminium, Aluminium Oxide, and Aluminium Hydroxide". *J Toxicol Environ Health B Crit Rev*. 2007; 10(Suppl 1): 1–269. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2782734/. Accessed April 10, 2019.

More importantly, petitioner did not justify that there are not any potential information needs from EPA, such as needs under TSCA for processing and use information reported to CDR as part of chemical prioritization, risk evaluation, and risk management under TSCA section 6.

The above factors weigh against establishing a partial exemption.

Consideration D: The availability of other complementary risk screening information.

Petitioner provides little evidence demonstrating that complementary risk screening information is available for aluminum oxide aside from past information on annual production capacity from ATSDR's Toxicological Profile for aluminum oxide.

Aluminum oxide is on OECD/Canada's DSL, but risk screening information complementary to CDR is limited. Fibrous forms of aluminum oxide are on Canada's National Pollutant Release Inventory (NPRI) with a use reporting threshold (10 tons). These data do not necessarily reflect activities in the U.S., and the available NPRI information (e.g., pollutant releases, disposals, and recycling) is more comparable to TRI than processing and use information reported under CDR.

The above factors lead EPA to conclude that the partial availability of complementary risk screening information is insufficient, which weighs against partially exempting aluminum oxide from CDR reporting.

Consideration E: The availability of comparable processing and use information.

Though petitioner claims that processing and use information collected under CDR would be available from other sources (specifically, ATSDR's Toxicological Profile), that information is not as current nor is it comparable to the level of detail in the exposure-related information provided in CDR. The European Chemicals Agency is collecting data regarding aluminum oxide use in Europe; while recent processing and use information for this chemical is available, albeit in a very generalized manner, it does not specify the amounts of aluminum oxide for each use, nor does it provide any quantitative value in regard to releases and/or exposures, and does not necessarily reflect processing and use activities in the U.S. Regarding potential information that could be comparable to the number of exposed workers reported under CDR, occupational employment stats are available from the Bureau of Labor Statistics, but this information is not site-specific or exposure-related.

Additionally, TRI information does not supplant CDR processing and use information. Aluminum oxide is listed on TRI, but only in fibrous forms. TRI provides limited information on quantities released related to the processing and use of the chemical, but not the types of exposure-related information that CDR provides. Data from the non-confidential 2012 and 2016 CDR database identified numerous industrial, consumer, and commercial uses (see Consideration F).

Given that processing and use information comparable to what is collected under CDR is not available, this weighs against granting the partial exemption.

Consideration F: Whether the potential risks of the chemical substance are adequately managed by EPA or another agency or authority.

Petitioner claims that the risks of aluminum oxide are adequately regulated by EPA and Occupational Safety and Health Administration (OSHA). Petitioner also states that fibrous forms of aluminum oxide are the only form of aluminum oxide that EPA has determined it has regulatory interest in addressing (i.e., listed on Section 313 of EPCRA) and that OSHA has established a permissible exposure limit for aluminum oxide dust. While it is true that aluminum oxide is regulated under other federal statutes, research needs remain associated with occupational exposure via inhalation. CDR processing and use information has the potential to help fill these information gaps. Therefore, it is not a certainty that the potential risks are currently adequately managed.

There are many uses for aluminum oxide and possibly many new uses that have not yet been reported. Examples of uses reported to CDR include (but are not limited to): abrasives, adhesives and sealant chemicals, fillers, finishing agents, functional fluids (closed systems), intermediates, oxidizing/reducing agents, paint additives and coating additives, pigments, plasticizers, and plating agents and surface treating agents. Trend analysis was completed from the available CDR processing and use information for aluminum oxide (2012 – 2016). The results show that the number of unique scenarios reported increased for industrial processing and use from 153 to 187 and for consumer and commercial use from 38 to 46.

Given that the diversity of scenarios is increasing, the variety of potential exposure pathways, and consequently the related risk associated with the processing and use of aluminum oxide is changing over time. These factors indicate a continued current interest in aluminum oxide and weigh against granting the partial exemption.

Additional Considerations:

Petitioner argues that EPA's original reasoning for denial has been resolved as reporting for aluminum oxide (including processing and use) was conducted in 2012 and 2016. While EPA has collected processing and use information for aluminum oxide for these two reporting cycles, there has been a stark increase in the number of processing and use scenarios, not to mention increased variability in these scenarios. As a result, exposure has changed as well. EPA continues to have interest in knowing and understanding the changes in these scenarios.

Regarding nanoscale materials specifically, petitioner describes that instead of proposing a section 4(a) test rule to evaluate aluminum oxide, EPA issued a final rule (82 FR 3641, January 12, 2017) that required one-time reporting and recordkeeping of existing exposure and health and safety information (e.g., specific chemical identity; production volume; methods of manufacture; processing, use, exposure and release information; and available health and safety data) on nanoscale chemical substances in commerce. Petitioner claims that this reporting (completed in August 2018), coupled with the information provided in the 2011 and 2015 CDR reporting years, provides EPA with the dataset needed to confirm a 'low current interest' in aluminum oxide. They also point out that if EPA at some point in the future were to propose and finalize a section

4(a) test rule for aluminum oxide, that rulemaking would supersede any partial reporting exemption provided under this request.

EPA disagrees that the information reported under the nanoscale materials reporting final rule supports a low current interest in aluminum oxide, or that this one-time reporting is sufficient to supplant CDR. Under the nanomaterials reporting rule, the details of how a substance is processed or used are not as extensive as that for CDR reporting. This reporting further provides that EPA does not have a low current interest in the processing and use information of aluminum oxide.

Conclusion: EPA has determined that the Agency does not have a low current interest in the processing and use information collected under the CDR rule for aluminum oxide. EPA considered the information included in the petition, but ultimately determined it to be insufficient for EPA's needs. EPA continues to maintain interest in the processing and use information for aluminum oxide. This determination is based on the totality of information available for the chemical substance, including an evaluation of all the considerations listed in 40 CFR 7l1.6(b)(2)(ii), and additional considerations petitioner noted.

In reviewing this petition and available supplementary information in regard to the Agency's current interest in the processing and use information of aluminum oxide, EPA determined that:

- The substance met OECD criteria for human health, environmental concerns, persistence, and is listed as inherently toxic to aquatic organisms;
- Research gaps exist and may require CDR processing and use information;
- Risk screening information complementary to CDR is insufficient;
- Processing and use information comparable to what CDR provides is not available from other sources;
- There is not enough evidence supporting that the potential risks are already adequately managed; and
- Based on trend analysis of available processing and use information, many uses for aluminum oxide exist and possibly many new uses have not yet been reported. These new, unreported uses are important for EPA to know. The number of unique scenarios reported to CDR, and therefore the variety of potential exposure pathways, for aluminum oxide's industrial processing and use has changed and increased considerably over time (2012 – 2016).