SMI

SORPTIVE MINERALS INSTITUTE

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Via Electronic Submission

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Office of Standards Regulations and Variances
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Comment of the Sorptive Minerals Institute (SMI); Mine Safety and Health Administration's Proposed Rule on Lowering Miners' Exposure to Respirable Crystalline Silica and Improving Respiratory Protection (Proposed Standard or Proposal

We are writing on behalf of the Sorptive Minerals Institute ("SMI"), a trade association representing manufacturers and marketers of absorbent clay products. Since 1988, SMI has served as the scientific research arm for the sorptive minerals industry. In this capacity, SMI has compiled a significant volume of independent academic and government research and collaborated with other researchers to develop and advance the scientific study of such topics as silica species characterization and the toxicology of respirable crystalline silica.

We are pleased to have the opportunity to comment on the Mine Safety and Health Administration's ("MSHA's" or "the Agency") Proposed Rule on Lowering Miners' Exposure to Respirable Crystalline Silica and Improving Respiratory Protection ("Proposed Rule" or "Proposal"). We urge MSHA to thoughtfully consider these Comments, as well as the testimony SMI presented at MSHA's August 21st Administrative Hearing, and the supplemental materials we submit with these Comments for your review, including, most importantly, the scientific studies and literature referenced herein and in *Appendices A and B* attached hereto.[1]

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[1] The following appendices are included with SMI's Comments:

- *Appendix A* (PowerPoint Presented at MSHA Administrative Hearing, August 21, 2023, Denver CO);
- *Appendix B* (List of Published Studies and Literature Relevant to MSHA Rulemaking);
- *Appendix C* (Comments Submitted to OSHA on February 11, 2014 regarding OSHA Proposed Rule on Occupational Health Standard for Crystalline Silica,78 Fed. Reg. 56274 (September 12, 2013); SMI Post-Hearing Comments submitted on June 3, 2014;and SMI Post-Hearing Brief submitted on August 18, 2014;
- *Appendix D* (OSHA Final Rule on Occupational Health Standard on Crystalline Silica); and
- *Appendix E* (Description of the geology and mineralogy of sorptive clay deposits with map showing their locations/geologic time chart).

Sorptive clays are a unique subset of clays that formed tens to hundreds of millions of years ago. The sorptive clays that are found in the United States, which exist in only a few geologic deposits in the country, have specific properties that render them extremely useful in a wide range of consumer products and commercial and industrial applications, including, for instance, clay-based pet litter, cosmetics, pharmaceuticals, animal feeds, specialized drilling muds used in well drilling, and environmental sealants for landfills and sewage lagoons. The industry is relatively small, with mining operations and/or processing/packaging facilities in only about 11 states. The industry employs less than 2,000 employees who mine, process or package[2] sorptive clays in approximately 40 facilities across those states. Accordingly, the sorptive clays industry makes up only a very small fraction of the U.S. mining industry.

While various forms of silica can be found in sorptive clays mined from these geologic deposits, ***<u>in all cases</u>***, the silica exists in either an amorphous form *(i.e.*, opal), appropriately not proposed to be regulated by MSHA, or in a crystalline form as geologically ancient quartz that is characterized by an aluminosilicate occluded surface which is physiochemically bound to the quartz making it an inseparable part of the quartz particle.

Quartz in sorptive clays does not occur as either pure quartz or fractured quartz (neither freshly fractured nor “aged”). Nor is it fractured in the mining or processing conducted by the sorptive minerals industry. Occluded quartz from sorptive clays is simply a different species of quartz from all other forms of quartz that are, appropriately, the focus of MSHA’s rulemaking. The differences between the occluded quartz found in sportive clays and other forms of quartz is critical to the toxicology of this material and its potential to adversely impact the health of workers exposed to it. To put it simply, there is no evidence to indicate that the occluded quartz from sorptive clay presents the health risk presented by other forms crystalline silica.

When OSHA performed its risk assessment in 2013-2016 to support a similar rulemaking to revise its silica standard, OSHA studied the type of occluded quartz found in sorptive clays and determined, based on the best available science at the time, that sufficient evidence did not exist to support regulation of this material. The agency therefore exempted sorptive clays from coverage under its 2016 silica standard. While OSHA recognized some questions remained about the toxicology of occluded quartz, even with authority to err on the side of caution and to build in a margin of safety, the agency determined that regulation of occluded quartz was not appropriate.

Since OSHA’s evaluation of occluded quartz found in sorptive clays, the science and understanding of the nature of crystalline silica and its toxicological mechanisms has advanced considerably. This science now even more definitively supports OSHA’s 2016 determination that regulation of occluded quartz in sorptive clays is not warranted.

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[2] Packaging typically occurs in distinct facilities that are not subject to MSHA regulation, but are under the jurisdiction of OSHA.

MSHA's rulemaking docket includes a review and evaluation of the health effects literature on crystalline silica. *See Review of Health Effects Literature,* Mine Safety and Health Administration, *Effects of Occupational Exposure to Respirable Crystalline Silica on the Health of Miners. Review of Health Effects Literature* (September 11, 2023 2:00 PM) https://www.regulations.gov/document/MSHA-2023-0001-1289,("RHEL"). This evaluation seems to clearly recognize that the nature of the surface of quartz particles is key to the potential toxicity of the material, and that occluded quartz, because of the physio-chemical make-up of its surface, does not present the same risk as that presented by other types of quartz. MSHA expressly states, "[p]hysical characteristics relevant to the toxicity of respirable crystalline silica primarily relate to its size and surface. Researchers believe the size and surface play important roles in how respirable crystalline silica causes tissue damage. Any factor that influences or modifies these characteristics may alter the toxicity of respirable crystalline silica by affecting mechanistic processes (OSHA 2013b). Occupational Safety and Health Administration, Docket OSHA-2010-0034, *Occupational Exposure to Respirable Crystalline Silica – Review of Health Effects Literature and Preliminary Quantitative Risk Assessment* (September 11, 2023,12:48 PM) https://www.regulations.gov/document/OSHA-2010-0034-1711. MSHA concludes that it agrees with OSHA's assessment of the risk of occluded quartz: "*After reviewing OSHA's rulemaking documents, MSHA agrees with OSHA's conclusion regarding the health effects associated with respirable crystalline silica exposure, and MSHA proposes the same exposure limit for all miners, as well as other requirements to protect miners' health."* Mine Safety and Health Administration, *Effects of Occupational Exposure to Respirable Crystalline Silica on the Health of Miners. Review of Health Effects Literature* (September 11, 2023 2:00 PM) https://www.regulations.gov/document/MSHA-2023-0001-1289 at 23. Yet, inexplicably, this critical evaluation does not seem to carry over to MSHA's Preliminary Risk Assessment and most definitely is not recognized in its Proposed Rule.

What is missing from MSHA's evaluation is an understanding of the underlying mechanism that causes crystalline silica to become toxic, something which is critical if MSHA is to successfully establish regulatory controls to mitigate the health hazard associated with crystalline silica. Based upon a review of the references in MSHA's Proposed Rule, and its supporting documentation, it appears that the Agency has not considered the latest science in the field of silica toxicity. A complete evaluation of this new science is essential for MSHA to understand toxicity of crystalline silica. An understanding of the mechanism of toxicity for crystalline silica is essential to develop a legally permissible revised standard that is properly scoped.

SMI's Comments present a summary of the best available science on, and the latest available study of, the nature and toxicology of crystalline silica and a review of the legal standard applicable to MSHA's rulemaking authority. Both the science (the facts) as well as the law indicate that MSHA should exempt sorptive clays from regulation under its final revised standard to Lower Miners' Exposure to Respirable Crystalline Silica. Policy and practical considerations relating to alignment of Department of Labor standards and compliance and enforcement considerations also strongly support exemption of sorptive clays from regulation under MSHA's final silica standard.

I. Introduction

Since 1988, SMI has concerned itself with the scientific questions surrounding the health effects of exposures to the clay minerals it mines and the products it makes. SMI has served as a leader in scientific research and is the leading storehouse of scientific work, information, and studies relevant to issues associated with the use and handling of sorptive clays. Through its Technical Committee, SMI has been heavily involved in crystalline silica research for over 35 years. During that time, SMI has produced a large body of research that has been presented at scientific conferences in the United States, Europe, and South Africa, and has been published in peer-reviewed scientific journals and has worked cooperatively with both state and Federal regulatory agencies.[3]

In addition to the work SMI has conducted and advanced, it also has closely monitored the study of crystalline silica by independent academic researchers. Due to the serious adverse health effects posed by quartz, cristobalite and tridymite in industrial settings, a wealth of independent scientific study has been generated that has focused on the physiochemical properties of crystalline silica and the mechanism by which it triggers adverse biological reactions.

While substantial, MSHA's Review of Health Effects Review confirms that MSHA has an incomplete understanding of the latest scientific research relevant to understanding the characteristics of crystalline silica that cause disease. For instance, and important to understanding occluded quartz, in describing the mechanistic process that leads to the development of silicosis and cancer, MSHA states that "[the] first step in this proposed process involves the action of ROS that often occurs on the surface of respirable crystalline silica. However, ROS may also be generated by activation of macrophages upon phagocytosis of the respirable crystalline silica." Mine Safety and Health Administration, *Effects of Occupational Exposure to Respirable Crystalline Silica on the Health of Miners. Review of Health Effects Literature* (September 11, 2023 2:00 PM) https://www.regulations.gov/document/MSHA-2023-0001-1289 at 36-37. MSHA's conclusion here is incorrect because it has not reviewed the latest science that considerably advances the understanding of the mechanistic processes that lead to disease.

By these Comments, SMI provides the latest scientific research to allow MSHA to more completely understand the risk of crystalline silica – what triggers disease and what does not. It is SMI's hope that a fuller and accurate understanding of the latest science in the field will allow MSHA to update its Health Effects Review and revise its Preliminary Risk Assessment to recognize that the geologically ancient, occluded quartz found in sorptive clays, like amorphous

[3] SMI has worked cooperatively with regulatory bodies in California and other jurisdictions to assist these agencies in developing an understanding of the relevant scientific data necessary to assess inhalation exposure issues related to sorptive clay products. In California, for instance, this work led to the issuance of a Safe Use Determination by the California Environmental Protection Agency's Office of Health Hazard Assessment for crystalline silica in sorptive mineral-based pet litter. SMI also met with OSHA on multiple occasions, as well as NIOSH, prior to the scoping of OSHA's proposed crystalline silica rule to discuss SMI's research on the nature quartz in clay.

silica, is a distinct species of crystalline silica that does not pose the risk that MSHA is focused on regulating with its revised silica standard.

II. The Critical Distinctions Between Silica in Sorptive Clays and Other Forms of Silica (Cristobalite; Tridymite; Fractured Quartz).

A. The Nature and Type of Silica in Sorptive Clays.

The sorptive clays mined and processed by SMI members were formed tens to hundreds of millions of years ago and are found in only a few clay deposits in the United States.[4] None of these clays have been exposed to temperatures higher than about 50 degrees Celsius during or since their formation. Typical of these deposits is bentonite, consisting predominately of smectite minerals. The location of the sorptive clay deposits used by the sorptive clay industry is shown on a map provided in *Appendix E.*

A portion of the silica contained within sorptive clays exists as opal, which is a non-crystalline silica hydrate. Opal does not have the organized structure or long-range periodicity required to be crystalline even though it may have short range domains of increased order that may resemble crystalline forms. Opal, along with other forms of amorphous, or non-crystalline silica, that are prevalent in sorptive clays, are not covered by MSHA's Proposed Rule.[5] The exclusion of amorphous silica in MSHA's Proposal is consistent with the long-recognized absence of a health risk associated with exposure to amorphous silica.

Sorptive clays do, however, naturally contain some amount of quartz, a crystalline form of silica which, when of respirable size, would be subject to MSHA's Proposed Rule. It is MSHA's evaluation of the health risk of this respirable quartz that is of concern to SMI. The concern centers on the fact that MSHA's Proposed Rule does not recognize the significance of the fact that the quartz present in sorptive clays exists in a uniquely distinct occluded form having an aluminosilicate surface that is physiochemically bound to the quartz and that this occlusion significantly mitigates the potential for deleterious health effects. For MSHA to conduct a meaningful, accurate and legally supportable risk assessment of the potential health effects associated with exposure to the silica present in sorptive clays, it is necessary for the Agency to understand the unique chemical and physical characteristics of the silica present in these clays and to evaluate the most current scientific literature on this subject. It is also critical that MSHA understand the mechanism by which crystalline silica triggers disease when exposures to this material occur.

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[4] No specific NAICS code delineates the sorptive clay industry. However, the category of clays covered by the moniker "sorptive clays" includes the following clay minerals: Bentonite, Attapulgite, Sepiolite, Calcium Montmorillonite, Sodium, Montmorillonite, Hectorite, Beidelite and Nontronite. SMI believes it is appropriate to exclude those who mine and process these clays from coverage under MSHA's revised silica standard.

[5] In excluding amorphous silica, MSHA recognized that not all forms of silica pose a risk that ought to be regulated, and that it is sensible to regulate only those forms which are known to cause a human health hazard.

B. Quartz in Sorptive Clays Exists in a Biologically Unavailable State with Limited Potential to Interact with Biological Systems Because of its Occluded Surface.

Broadly, the crystalline silica present in sorptive clay deposits may result from three distinct processes. First, it can form when certain types of igneous rocks containing quartz are weathered, *in situ*, into clay deposits. Such deposits can retain these quartz crystals in the clay matrix resulting in "residual quartz." Second, quartz crystals may have been eroded from distant deposits, carried in by rivers and streams, and co-deposited with volcanic ash which was later altered to clay resulting in "detrital quartz." Third, and most commonly found, quartz can form at the same time as the clay when volcanic ash, that has been dissolved after having fallen in salty water, reprecipitates as clay rock. This type of precipitated quartz is termed "authigenic quartz", meaning that it was formed at the same time as the other constituents of the rock.

Regardless of the variety of quartz contained in sorptive clays, it exists in a form that is notably distinct from other forms of silica that MSHA is appropriately proposing to regulate. This is because all sorptive clay quartz has been in intimate contact with the clay in which it occurs for about 10 to 110 million years, depending upon the deposit, has crystal surfaces that are in physicochemical equilibrium with the environment of the clay matrix and has not been fractured.

A prime example is bentonite, the most common type of material mined and processed in the sorptive clay industry. Bentonite is a clay-rich rock produced when rhyolitic volcanic ash that had fallen in brackish or saltwater dissolved and then re-precipitated out of solution. The resulting rock is composed predominately of the clay mineral montmorillonite along with a variety of other minerals including feldspar, mica, gypsum, opal (an amorphous form of silica) and quartz. All of these minerals were formed in place and at the same time (authigenically). The result of this process is a complex mixture of minerals which have been in intimate contact with each other since they were formed. Although some younger deposits exist, most bentonite used by the sorptive clay industry was formed during the early to mid-Cretaceous period about 90 to 110 million years ago.

The quartz particles in bentonite have had millions of years to react with and come to equilibrium with their environment, and to develop surface occlusions consisting of "adventitious" ions such as aluminum, iron, sodium and others. The presence of these ions changes the surface of the particles so that they no longer exhibit the rigid crystalline SiO2 structure that is integral to the quartz grain and is not itself quartz. In addition, aluminosilicate occlusions also may be present on the surface of authigenic quartz particles. Even when the quartz particles are separated from the clay matrix in which they resided, they continue to retain their elemental and aluminosilicate occlusions.

C. Mining and Processing of Sorptive Clays in Industrial Settings Does Not Alter the Occluded, Coated Nature of the Quartz.

Various types of manufacturing or processing operations use high heat calcination and extreme crushing or grinding that can fundamentally change the nature of silica particles. For example, when either amorphous silica or quartz is heated to a sufficiently high temperature (in the range of 1470 degrees Celsius) it can convert to cristobalite, a biologically aggressive form of crystalline silica. Further, when quartz is crushed, reactive fractured surfaces are created, leading to significantly higher bioactivity. In fact, the biological reactivity of quartz in occupational settings is now thought to be caused by the fracturing of quartz grains in industrial processes.

Numerous industries engage in the types of industrial processing that fracture quartz. Processes such as crushing, cutting, grinding, drilling and polishing of siliceous hard rock, or hard rock containing materials, such as cured concrete, all produce fractured crystalline silica particles of respirable size which have the potential to become airborne and be hazardous. Additionally, processes, such as calcination, high firing to produce some types of brick and ceramics and contact with molten metal in metal casting, all generate high temperatures in silica-containing materials that are sufficient to cause them to thermally fracture or change the nature of the silica and also make it hazardous.

The sorptive clay industry does not employ these or other mining or processing methods that have the potential to fracture or change the nature of the quartz in the clay. In crude form, sorptive clays are inherently very soft materials. Bentonite, for example, has a Mohs hardness of between 1 and 2 on the 10-point Mohs scale, depending on its moisture content. In contrast, quartz has a Mohs hardness of 7. As a result, whether during mining or processing, clay rocks break through the softer clay matrix and not through the very tiny and much harder quartz particles that they may contain. Further, during drying, sorptive clays are never allowed to reach temperatures above about 250° Fahrenheit because higher temperatures would destroy the very qualities of the sorptive clays that render them useful as commercial products. This is far below the temperatures required to either thermally fracture quartz particles or create the more hazardous crystalline silica forms, cristobalite and tridymite. For these reasons, the mining and processing methods used by the sorptive clay industry does not alter the distinct characteristics of the geologically ancient aluminosilicate occluded quartz found in the clay it utilizes.

III. The Best Available and Most Current Scientific Studies Demonstrate That Occluded Quartz Does Not Pose a Risk Similar to that Posed by Freshly Fractured Quartz.

A voluminous body of scientific work demonstrates the critical distinction in the risk potential between fractured quartz and the unfractured, geologically ancient, aluminosilicate occluded quartz in sorptive clays. Much of this work was considered by OSHA in its risk assessment of crystalline silica and led to OSHA's decision to exempt sorptive clays from coverage under that agency's revised silica standard. Since OSHA's revised standard was promulgated, additional research conducted in this field has led to a seminal discovery that addresses the question of "how" quartz causes disease.

This section of our Comments highlights and summarizes a number of important studies in this area and describes the consensus scientific determinations related to the difference in risk potential between fractured (freshly fractured or mildly aged) and unfractured and occluded quartz. To develop a properly scoped regulation, MSHA must consider and carefully evaluate this science.

A. Studies on Significance of the Surface and Physio-Chemical Characteristics of Quartz

- An important study of the surface characteristics of silica in the sorptive clay industry's clays was published by *Wendlandt et al.*, 2007. In this study, which was not cited by MSHA, the surface of hundreds of individual quartz grains of different sizes and origins, all taken from bentonite, was meticulously studied. Findings from this study show:

  - Montmorillonite clay surface coatings are ubiquitously present;
  - The coatings are extremely persistent resisting long duration physical and chemical dispersing and acid washing;
  - Montmorillonite coatings cover all external surfaces of quartz grains regardless of the size of the grain (2-38 µm);
  - Mechanical processing appears to have no effect on the montmorillonite surface coatings.

This study concluded that *"... the presence of montmorillonite coatings has the potential to mitigate quartz toxicity in the lung."*

- Three animal studies (*Porter*, 2005; *Shoemaker*, 1995; and *Vallyathan*, 1995) compare the toxicity of respirable, *freshly fractured* silica to that of respirable *"aged"* silica (*i.e.*, silica that has been aged for 2 months or less). *These studies uniformly state that the freshly fractured silica has significantly greater toxicity than the aged silica, even though it had only been aged for no more than 60 days.* In contrast to the 60-day (or less) aged silica used in these studies, the geologically ancient, occluded quartz found in sorptive clays is tens of millions of years old and has unfractured surfaces that have been in physicochemical equilibrium with their environment throughout that time.

- *Miles, et al.*, 2008, characterized the physicochemical properties of freshly fractured quartz and quartz with geologically ancient aluminosilicate occluded surfaces from bentonite that was used in toxicological research that was discussed in *Creutzenberg, et al.*, 2008. Together, the *Miles, et al.*, 2008,[6] and *Creutzenberg, et al.*, 2008,[7] studies, published

[6] Miles *et al.* (2008). Physicochemical and Mineralogical Characterization of Test Materials used in 28-Day and 90-Day Intratracheal Instillation Toxicology Studies in Rats. Inhalation Toxicology, 20:981-993.

[7] Creutzenberg *et al.* (2008). Toxicity of a Quartz with Occluded Surfaces a 90-Day Intratracheal Instillation Study in Rats. Inhalation Toxicology, 20:995-1008.

together as companion papers, form a unique and robust comparison of the toxicological characteristics of quartz from bentonite clay and crushed and fractured quartz (DQ12) that has been widely used in animal toxicology studies for many decades.

B. Relevant *In Vitro* And Animal Studies

Geh, et al., (2006), exposed human lung fibroblasts *in vitro* to relatively high concentrations of untreated and modified bentonite containing varying levels of quartz and with differences in the presence and types of transition metals. These authors found only very low levels of genotoxicity, as measured by micronucleus assays, in any of the tested samples. They also found that untreated samples with less than 1 percent quartz showed no increase in micronucleus formation.

Two animal studies by *Creutzenberg, et al.* (2003; 2008) are consistent with the findings of *Geh et al*. These studies found that geologically ancient, aluminosilicate occluded quartz was substantially less toxic than freshly ground crystalline silica[8] in rats after intratracheal instillation with follow-up for 28 days (2003) and 90 days (2008). In these studies, significant effort was made to extract quartz from a bentonite clay, using an aqueous dispersion method, to avoid altering the surface characteristics of the quartz particles (quartz isolate) by chemical or mechanical processing. The quartz isolate obtained was used in single high-dose rat instillations studies to assess the toxicological differences between this type of occluded quartz and freshly fractured quartz. These studies provide sound evidence that cytotoxicity and inflammation were significantly less severe in animals dosed with the occluded quartz isolate as compared to "freshly fractured" quartz.

Specifically, the crushed quartz positive control (DQ12) induced a persistent, strongly progressive inflammatory response and significant tissue damage, while the response to the occluded quartz isolate, at the same dose, was modest, non-progressive and began to resolve about 3 days after dosing. While the dosing used in these studies was specifically designed to elicit an inflammatory response, the results show that the response for occluded quartz is dramatically different and far less potent than that of fractured or crushed DQ12 quartz. The mode of action for silicosis and lung cancer from crystalline silica requires prolonged, progressive inflammatory response. The results from Creutzenberg have confirmed that geologically ancient quartz with aluminosilicate occluded surfaces is far less biologically reactive and produces a significantly lower inflammatory response in test animals. As a result, it is reasonable to expect that exposures to geologically ancient, aluminosilicate occluded quartz from clays at the current PEL are sufficient to continue to protect miners from material impairment of health, including lung cancer and silicosis.[9]

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[8] The "freshly ground" crystalline silica used in the *Creutzenberg* studies was crushed DQ12 quartz that, at the time of use, was 30 years old.

[9] Data from the industry support this conclusion. SMI member companies have operated over 80 years without one known instance of silicosis among the industry's historic or current workforce.

C. Epidemiological Data Do Not Support an Association Between Silicosis and Exposure in the Sorptive Clay Industry.

Sorptive Clays Studies

Exposure of workers in the sorptive clay industry to crystalline silica has not been extensively studied due to the lack of observed health effects in the industry. However, one retrospective cohort study conducted by NIOSH (*Waxweiler, et al*. 1988[10]) evaluated the mortality of workers in a sorptive mineral mine and processing facility in South Georgia. Geometric mean exposures to total dust ranged from 1.15 to 15.9 mg/m^3 with a quartz content of four to eight percent. This study retrospectively followed a cohort of 2,302 males, employed for at least 1 month, between 1940 and 1975 in an attapulgite mine and milling facility with follow-up through 1975. This study was focused on the fiber-like aspect of attapulgite and not on the question of the toxicology of the quartz this clay mineral contained.

Waxweiler found, "[a] significant deficit of nonmalignant respiratory disease was observed, and no excess nonmalignant respiratory disease, regardless of presumed dust exposure level, induction-latency period, or duration of employment."[11]

Several reviews of worker exposures to crystalline silica have recognized the lack of silicosis risk among clay workers with exposure to clay dust, including exposures to Fullers earth, bentonite, montmorillonite, and attapulgite (ACGIH, 1991; USEPA 1996; IARC 2005). The World Health Organization's (WHO) International Agency for Research on Cancer (IARC) prepared a Monograph reviewing health effects for workers exposed to kaolin and bentonite (IARC 2005). This Monograph recognizes that studies of workers exposed to sorptive clays have not identified significant silicosis risk. With regard to bentonite, the most prevalent form of sorptive clay mined in the industry, IARC (2005) concludes:

> With regard to bentonite, comparable montmorillonite pneumoconiosis [similar to that induced by exposure to kaolin] has not been consistently reported. Based on its surface chemistry, lack of fibrogenicity in experimental systems and limited human findings, inhaled bentonite is likely to be less dangerous to humans than kaolin.

It is further noteworthy that IARC concluded that the risk posed by kaolin was approximately ten times less than that of quartz, and that standards should be protective of nuisance dusts. IARC' s review of bentonite and kaolin supports the concept that exposure to

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[10] Waxweiler, *et. al.* (1988) Am J Ind Med. 13:3-5-315.

[11] Noting that smoking had not been considered in the study, the authors also found that, although a significant excess in lung cancer was observed among whites, a significant deficit occurred among nonwhites. Further, although the number of whites was greater than the number of nonwhites in the cohort, the number of nonwhites with high exposure jobs outnumbered the whites by more than fourfold. The SMRs for lung cancer overall were neither significantly elevated (SMR = 119), nor were they elevated for cohort members in the high exposure group (SMR = 105) or among those with longer latency (SMR = 100).

these clays, even though they contain quartz, does not pose a risk of silicosis or lung cancer.

D. Additional Scientific Studies That Help to Explain Why Disease is Not Initiated by Geologically Ancient Occluded Quartz in Sorptive Clays

Numerous researchers over the past 40 years have found a relationship between the toxicity of crystalline silica and the surface characteristics of crystalline silica particles. Following is a short list of references to some of the historic research as well as the most recent scientific study on this topic, all of which should be carefully evaluated by MSHA before finalizing its revised silica standard:[12]

In 1987, *Kriegseis et al*. determined that the amount of uncontaminated quartz surface was the important parameter for determining the pathogenic behavior of respirable quartz dust. They found that removal of impurities from quartz particles, using chemical treatment, resulted in an increase in cytotoxic effect.

Also in 1987, *Fubini et al*. found that surface radicals formed on the surface of mechanically ground quartz, resulting in homolytic cleavage of Si-O-Si bonds, caused the quartz to exhibit peculiar reactivity with biological molecules causing structural modifications. They suggested that this, more than crystallinity, was the primary cause of SiO2 toxicity.

Costa, et al., 1991, described a new surface site on the surface of freshly cleaved or chemically etched quartz, but which was absent on crystal growth faces or samples annealed at high temperature. They noted that there was a correspondence between the presence of this site on variously treated quartz dusts and their fibrogenicity suggesting a relationship between the site and silica pathogenicity.

Noting that they had previously reported that crushing or grinding crystalline silica resulted in the generation of silica-based radicals on the particulate surface and that these radicals could generate hydroxyl radicals in aqueous solution, *Vallyathan et al.*, 1991, reported that freshly ground silica was significantly more cytotoxic and is a more potent activator of alveolar macrophages that comparably sized aged silica. They found that Prosil 28, an organosilane was effective in reducing cytotoxicity and activate macrophages. They suggest that surface radicals associated with freshly cleaved silica dust may be an important factor in the induction of pulmonary disease and that treating silica dust particles with coating agents may substantially decrease toxicity.

In a 1998 review paper, *Donaldson and Borm* state that mechanistic studies they reviewed demonstrated that the biological effects of quartz can be understood in terms of surface reactivity. They particularly emphasized the ability of quartz to generate free radicals and cause oxidative stress and the fact that this could be modified by a range of substances that affect the quartz surface, noting that some of these modifying substances could originate from other minerals. Considering these findings, they proposed that the hazard posed by quartz was not a constant entity, but rather one that may vary dramatically depending on the origin of the silica sample or its contact with other chemicals/minerals.

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[12] These studies are included in the reference list appended to these Comments.

Fubini et al., 2001 studied the effect of origin, crystallinity and state of the surface of silica on the generation of reactive oxygen species and morphological transformation of mammalian cells. They found that the variability in the cellular response elicited by different silica sources is more related to differences in the state and number of active sites on the surface of the particles than to the crystal structure of the bulk material.

Also in 2001, *Gocmez et al*. compared the crystal morphology and crystallinity of freshly ground quartz and naturally occurring quartz in ball clay using scanning electron microscopy and X-ray diffraction. They found that freshly ground quartz particles had clean, highly angular, sharp edges and a high degree of crystallinity as measured by their Murata ratio. In comparison, they found quartz from ball clay was more rounded, was enclosed by kaolinitic clay, making it difficult to distinguish from kaolinite particles, and had a much-reduced Murata crystallinity.

Albrecht et al., 2005 investigated the significance of the particle surface reactivity of respirable quartz dust in relation to the *in vivo* generation of reactive oxygen and reactive nitrogen species (ROS/RNS) and the associated induction of oxidative stress responses in the lung. They found that significantly reduced levels of H2O2 and nitrite were observed in rats treated with either saline or the surface-modified quartz preparations, when compared to rats treated with non-coated quartz, providing further *in vivo* evidence for the crucial role of particle surface properties in quartz dust-induced ROS/RNS generation by recruited inflammatory phagocytes. They stated that pulmonary ROS and RNS release is considered as a crucial and unifying factor in the quartz-induced adverse health effects, including fibrogenicity and carcinogenicity.

In 2018 *Weber, et al*. investigated the toxicology of several synthetic amorphous silicas (SAS) in a 13-week subchronic rat inhalation study with multiple recovery period sacrifices (13, 26, 39 and 52 weeks). They reported that, while a high level of multifocal fibrosis and multifocal pleural mesothelial hyperplasia was found in test animals treated with quartz after the 52-week recovery period, animals treated with SAS sowed no progression toward fibrogenesis and exhibiting only sporadic, transient fibrogenesis that was comparable to that observed for the control group. They concluded that in contrast to quartz, the adversity created by SAS was fully reversible after 52 weeks of recovery.

In a series of reports *Pavan et al*. have critically evaluated the physicochemical properties of quartz in an attempt to define the cause of its sometimes-aggressive toxicology.

Pavan and Fubini, 2017, reviewed the state of knowledge at the time, concluding that the variability of quartz hazard could be fully justified by the large variations occurring in surface silanol distribution, implying different levels of inflammation. They stated that techniques were then available (FT-IR and NMF spectroscopy) to identify active silanol sites allowing prediction of the toxicity potential of different silica dusts and the efficiency of various detoxification methods that had been proposed.

Pavan et al., 2018a and 2018b, noting that all crystalline silica sources are not equally pathogenic, reported that synthesized respirable size quartz crystals with pristine crystal faces did not show biological activity in cellular tests while mechanical grinding of these same crystal samples markedly increased their biological activity. They proposed that irregularly distributed surface silanols produced **by grinding** contributed to membrane damage, inflammation and initiation of silica related disease. (Emphasis added)

Pavan et al.(17 coauthors), 2019, reported the conclusions of a workshop on "The puzzling issue of silica toxicity: are silanols bridging the gaps between surface states and pathogenicity?" The workshop concluded:

- fracturing of silica particles induces a perturbation of the regular crystalline face, generating, upon contact with atmospheric components, specific silanol populations (slightly-interacting and isolated silanols), which impart membranolytic and inflammatory activity to the respirable CS particles

- impurities at the surface of some CS (cristobalite), including substitution of Al and/or Na and occlusion of particle surfaces by Al-rich accessory minerals, likely influences the H-bonding potential of silanols at the particle surface and can reduce toxicity

- the toxicity of CS particles can effectively be reduced by surface coating processes masking silanol functionalities, also at the industrial level.

Pavan's more recent work considerably advances the understanding of the mechanism for disease and answers some questions that theretofore had not been understood. *Pavan et al*., 2020, identified a unique subfamily of silanols as the major determinant of silica particle toxicity. They found that this population of "nearly free silanols" (NFS), which appears on the surface of quartz particles **upon fracture,** can be modulated by thermal treatments and that the local density of silanols, not their total amount or average density, determines the toxic activity of silica dusts." Importantly, they also found that pure quartz, grown to respirable size, does not induce lung inflammation. They concluded that ***"Surface NFS emerge as the elusive element that reconciles the enigmatic inflammatory responses observed with both crystalline and amorphous silica in several experimental studies*."** (Emphasis added)

Pavan et al., 2022, studied the interaction of silica particles with variable amounts of membranolytic surface silanols (NFS) and model membranes with different molecular complexity and charge. They found that the presence of selective epitopes on phospholipid membranes irreversibly interacted with NFS on silica when they exhibited a zwitterionic phosphocholine but not when a negatively charged phosphoserine was exposed resulting in a linear correlation between the amount of adsorbed DOPC, a specific phosphocholine, and the relative amount of NFS on the silica particles. They state that, consistent with spectroscopic results, this finding defines NFS as the specific surface site responsible for the interaction with membrane phospholipids and that the data supports the specific and selective interaction that requires both the presence of NFS on silica surface and the presence of a definite molecular conformation and charge distribution of the phospholipid.

Pavan et al., 2023, evaluated the physicochemical characteristics and membranolytic activity of five crystalline silica polymorphs. They found that differences in membranolytic activity observed among the polymorphs may be ascribed to differences in the nature of the exposed surface and, specifically, to differences in the amount and distribution of NFS. They stated that while the crystal structure of the polymorphs should partially determine silanol distribution, in a real scenario NFS might be due to mechanical fragmentation and or thermal treatment used to obtain silica particles from raw materials. Pavan states that they modulated the amount of NFS on the polymorphs using thermal treatments thereby demonstrating that silica membranolytic activity positively correlated with the amount of NFS **for all crystalline silica polymorphs**. (emphasis added) They suggesting that, for all crystalline silica polymorphs, membranolytic activity is NFS mediated and conclude noting, "Overall, these findings contribute to the molecular understanding of the toxicity mechanism of silica-based minerals, and might be helpful for predicting and controlling the hazard associated to quartz and cristobalite, which are included in the IARC classification of human carcinogens."

In a literature review, *Poland et al*., 2023 evaluated the role of pulmonary inflammation as a predictor of particle induced lung pathology focusing on crystalline silica and amorphous silica. They found that the response time course following exposure was critical to understanding the potential pathology of these materials. They cite numerous studies which show that the time course for respirable crystalline silica exposure reflects an immediate acute inflammatory response which is progressive and continues to increase over the post exposure period, while the time course for amorphous silica exposure shows an initial acute inflammatory response which is non-progressive and resolves over the post exposure period. They conclude that the triggering of an acute inflammatory response does not equate to a definitive pathological outcome such as disease and suggest that current testing guidelines be extended with a recovery period that allows inflammation to resolve or progress into altered structure and function such as fibrosis.

E. Unpublished Research Provided to OSHA and MSHA During Oral Testimony

During its oral testimony on OSHA's proposed crystalline silica rule making in 2014, SMI provided OSHA with high resolution TEM dark field and light field images of geologically ancient, aluminosilicate occluded quartz particles from bentonite obtained by Hochella and Murayama, 2010, which illustrated in gray scale the nature of the quartz – aluminosilicate occlusion relationship. Additional TEM-EDS imagery was also provided which defined the chemical nature of the core and occlusion layer in these quartz particles. This imagery was also presented to MSHA in oral testimony given on August 21, 2023 at its Denver, CO hearing. Additionally, at that hearing new imagery obtained by Berti and Hochella, 2017 and 2018, and Cantando, 2020, was provided to MSHA which showed TEM-EDS false color elemental mapping of occluded quartz from bentonite as well as quartz DQ12. Here, concentrations of silicon atoms, indicative of quartz, and aluminum atoms, indicative of aluminosilicate were clearly visible providing clear confirmation of the nature of the core and occlusion layer of the occluded quartz from clay as well as the lack of any such layer on the quartz DQ12. This data is hereby incorporated into this written testimony.

Research Summary

Taken together, the body of research described here, in Section III, confirms the following key foundations for MSHA's determination of the scope if its revised silica rule:

- Crystalline silica particles must be fractured in order to have adverse toxicological properties
- Unfractured quartz does not have toxicological properties
- Fracturing crystalline silica particles generates nearly free silanols (NFS)
- NFS bind with sites on cell membranes initiating membranolytic activity
- Crystalline silica membranolytic activity is mediated by NFS present on fractured surfaces
- The presence of contaminating ions, such as aluminum, and surface occlusions, such as aluminosilicate, on crystalline silica particles mitigates their membranolytic activity
- The unfractured, geologically ancient aluminosilicate occluded quartz from clay has a toxicological time course profile similar to that of unregulated synthetic amorphous silica (SAS)
- The time course profiles of SAS and unfractured, geologically ancient aluminosilicate occluded quartz from clay are vastly different from the time course profile of fractured quartz, which should be the focus of MSHA's rulemaking
- The fractured quartz used in toxicological studies and the unfractured, geologically ancient, aluminosilicate occluded quartz from clay have significantly different physicochemical and toxicological profiles
- The aluminosilicate occlusion on quartz particles from bentonite is an intrinsic part of the quartz particle, is connected to the quartz core at the atomic level and is inseparable from it

IV. Coverage of Sorptive Clays Under MSHA's Final Silica Standard Likely Would Be Legally Impermissible Under the Mine Safety & Health Act and the Administrative Procedures Act.

In light of the large consensus in the scientific community regarding the absence of significant risk posed by industrial exposures to occluded quartz, a decision by MSHA to include sorptive clays within coverage of a final silica standard would quite likely be legally impermissible under both the Federal Mine Safety and Health Act of 1977 ("Mine Act"), 30 U.S.C. § 801 *et seq.* (1977) as well as the Administrative Procedures Act ("APA"), 5 U.S.C. § 555 *et seq.* (2006). While MSHA has flexibility to consider regulatory options during the proposed rulemaking stage, a final safety and health standard must meet all legal rulemaking prerequisites and limitations established by Congress. The Mine Act and the APA likely prevent application of the revised silica standard to the sorptive clay industry for the following reasons.

A. The Standard Would Not be Based on the Best Available Evidence and Would Not Reflect the Latest Available Scientific Data in the Field.

Section 101(a)(6)(A) of the Mine Act establishes the bounds of MSHA's authority to promulgate regulatory standards to protect miners from exposure to toxic materials. While providing MSHA with broad authority and significant discretion in establishing occupational health standards, that authority is not limitless. Section (6)(A) states, in pertinent part:

> The Secretary, in promulgating mandatory standards dealing with toxic materials or harmful physical agents under this subsection, shall set standards which most adequately assure ***on the basis of the best available evidence*** that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standard for the period of his working life.

30 U.S.C. § 811(a)(6)(A). Congress further mandated that when MSHA promulgates safety and health standards, it must consider "**the latest available scientific data in the field.**"

While caselaw recognizes the discretion given to MSHA under the Mine Act to promulgate safety and health regulations, it also sets clear guide posts within which MSHA is bound to operate. In *National Min. Ass'n v. Secretary, U.S. Dept. of Labor,* 812 F.3d 843, 866 (11th Cir., 2016), for instance, in reviewing MSHA's dust standard, the Court held that MSHA's statutory requirements to base a rule on the best available evidence "are significant, and … failure to address them would require us to vacate the rule." *Id. at 866.* In reviewing whether the agency had based it's rule on the best available evidence and latest available scientific data in the field, the Court stated that, even though a proper amount of deference would be granted to the agency, it would not validate the agency's action if it "exhibit[ed] 'a clear error of judgment.'", *Id.* at 873.

Similarly, in *Kennecott Greens Creek Mining Co. v. Mine Safety and Health Admin.*, 476 F.3d 946, 954 (D.C. Cir., 2007), the D.C. Circuit conducted a thorough analysis to ensure that MSHA has considered the best available evidence in promulgating its diesel particulate matter ("DPM") standard. While in that case the Court found that MSHA met its "best available evidence" burden, it concluded so only after reviewing the record and finding that MSHA had analyzed 47 epidemiological studies (from 1957 to 1999) as well as two "meta-analyses" that aggregated the data from the earlier studies" and also that it had "reasonably explained why it discounted the findings of the six studies that did not find a causal link between DPM exposure and lung cancer risk …Three of these studies did not allow for a sufficiently long latency period between exposure and evaluation, and a fourth study used too small of a cohort. And five of the six 'negative' studies did not have statistically significant results, whereas 25 of the 41 'positive' studies did find a statistically significant link between DPM exposure and lung cancer risk." *Kennecott Greens Creek Mining Co. v. Mine Safety and Health Admin.*, 476 F.3d 946, 954 (D.C. Cir., 2007).

MSHA correctly points out that the "duty to use the best available evidence …cannot be wielded as a counterweight to MSHA's overarching role to protect the life and health of workers in the mining industry. RHEL, p.3. Notwithstanding, it is also true that speculation about risk based on data from other industries cannot be used to leapfrog over the important obligation to identify a material impairment based on the best available evidence and most recent scientific research in the area for the industries that the agency intends to regulate. The revised silica standard MSHA has proposed is not based on the best available evidence, and does not consider the latest available scientific data in the field, on the toxicology and pathogenicity of the unfractured, geologically ancient, aluminosilicate occluded quartz from sorptive clay species of crystalline silica. While MSHA considered some of the scientific research on the mechanisms of action that render crystalline silica toxic and biologically available, the agency failed to consider a number of critically important studies that demonstrate and conclude that abundant silanol groups, in the form of nearly free silanols ("NFS") are fundamental to triggering the process that ultimately leads to the health hazard and that *fracturing of crystalline silica particles is a critical step that introduces NFS.* Yet occluded quartz in sorptive clays is not fractured, neither in the clay formation in which it exists nor during the mining and processing of the material to form sorptive mineral-based products.

Some of the most important studies not considered, or at least not properly evaluated or understood, by MSHA are listed in *Appendix C*.

Beyond this, and somewhat ironically, *MSHA's own evaluation* of the studies it did consider seems to conclude precisely the opposite of MSHA's proposed rule, which is that occluded quartz in sorptive clays *would not and does not* pose the health risk posed by fractured quartz. Confusingly, MSHA offers no "reasoned explanation" (or even any rational explanation whatsoever) for why the agency included occluded quartz from sorptive clays in the proposed rule in light of its RHEL.

Accordingly, because the best available evidence and the latest available scientific research in the surface properties of quartz, including quartz from sorptive clays, and their toxicological implications was not adequately considered and weighed by the agency, any final rule MSHA promulgates without careful evaluation of this evidence would be legally flawed and impermissible under the Mine Act.

B. MSHA Could Not Support a Finding of Material Impairment from Ancient Occluded Quartz Found in Sorptive Clays

As MSHA is well aware, before promulgating an occupational health standard for silica, it must first determine that the substance it intends to regulate will pose a risk of material impairment of health or functional capacity to a miner if he were to be exposed to the substance over his working life:

> The Secretary [of Labor], in promulgating mandatory standards dealing with toxic materials or harmful physical agents under this subsection, shall set standards which most adequately assure on the basis of the best available evidence that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards

dealt with by such standard for the period of his working life.

30 U.S.C. 811(a)(6)(A). While there is little doubt that MSHA's risk assessment provides sufficient support for a threshold finding of the risk of material impairment of health for workers who are exposed to cristobalite, tridymite or fractured quartz in many industrial settings, the agency has made no such threshold finding with regard to the sorptive minerals industry. As recognized by OSHA, there is neither epidemiological nor animal study evidence of such risk applicable to the sorptive clay industry,[13] nor does the toxicological study of quartz provide such support. In fact, literature shows quite the opposite. While MSHA is not required to develop with certainty or precision uncontroverted evidence demonstrating the risk of material impairment of health, it must at least provide a "rational connection between the facts found [the evidence of risk] and the [regulatory] choices made." *Kennecott Greens Creek Mining Co. v. MSHA*, 476 F.3d 946, 954 375 U.S. App. D.C. 13, 16 (D.C. Cir. 2007). In other words, before establishing regulations, it must ensure that its regulatory choice is not based on faulty assumptions or factual foundations. *Id.* at 952. *See also* 30 U.S.C. 811(a)(6)(A).

MSHA has made no such rationale connection at this proposed stage of rulemaking. And the Agency has based its proposal on a faulty assumption, lacking in sound factual foundation, that crystalline silica found in sorptive clays poses a material risk of health to the employees who are exposed to it in the sorptive minerals industry. Even though MSHA seems to recognize key distinctions in the characteristics and nature of occluded quartz from other species of quartz, it uses a broad brush to ignore those distinctions in finding a material impairment of health risk for *all miners.* MSHA states that "its review included more than 600 studies that explore the relationship between exposure to respirable crystalline silica and the resulting health effects for a variety of industrial workers, including more than a dozen for mining that constitute the MNM and coal mining sectors." However, none of these studies explore the exposure of sorptive clay minerals industry workers. SMI is aware of only one epidemiological study, not cited by MSHA, that focuses on the sorptive clay industry. This study by *Waxweiler et al., 2007* was focused on attapulgite mining and processing and the potential of the elongate crystal habit of this clay to provide a human health hazard. The authors reported that no such hazard was found.

While it is not only allowable, but important for MSHA to err on the side of caution in protecting miners from serious adverse health effects and impairments, it cannot apply a regulation to an industry where, if called upon to do so, it simply could not identify scientific support for that regulation. This is not a case of two conflicting viewpoints backed by scientific study for each; this is a case where the voluminous body of scientific study is one-sided and compelling.[14] Unfounded concern based on the lack of precise scientific certainty is not a legally

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[13] With regard to evidence of material impairment of health from lung cancer, MSHA concludes that "[t]he strongest evidence comes from the worldwide cohort and case-control studies reporting excess lung cancer mortality among workers exposed to respirable crystalline silica in various industrial sectors, confirmed by the 10-cohort pooled case-control analysis by Steenland et al. (2001a), the more recent pooled case-control analysis of seven European countries by Cassidy et al. (2007), and two national death certificate registry studies (Calvert et al., 2003 in the United States; Pukkala et al., 2005 in Finland). RHEL, pp. 13-14. No clay mineral-related cohorts are covered by this pooled case analysis. Similarly, for silicosis, MSHA has no data showing any significant cases of silicosis from the sorptive clay minerals industry.

[14] MSHA seems to, perhaps inadvertently, set up a red herring in its RHEL, where it recognizes and agrees

sufficient foundation to expand coverage of a final silica standard to the sorptive clay industry.

C. Final Standard Covering Sorptive Clays Would Run Afoul of OSHA's Existing Silica Standard, Creating Bad Policy and Non-Sensical Compliance and Enforcement Challenges.

Promulgation of a final standard covering sorptive clay facilities also would violate MSHA's statutory obligation under the Mine Act to take into consideration the experience gained under other safety and health laws before promulgating a new standard. *See* 30 U.S.C. §811(a)(6)A) ("… other considerations shall be the latest available scientific data in the field, the feasibility of the standards, ***and experience gained under this and other health and safety laws***."). Undoubtedly, MSHA should have – but seemingly did not – take into consideration its "sister" agency OSHA's decision to exempt sorptive clays from the equivalent standard OSHA promulgated in 2016. While MSHA most clearly modelled it's Proposed Rule on OSHA's final standard, it inexplicably ignored – with neither explanation nor support – OSHA's careful decision to exclude sorptive minerals from coverage under the its standard.[15] If finalized as proposed, MSHA and the regulated community will not have benefited from the "experience gained" by MSHA's counterpart agency within the Department of Labor in this field of technical risk assessment, an area where OSHA, undeniably, has credible stature and expertise.

The consequences of failing to exempt the sorptive minerals industry from its revised silica standard would be the creation of dueling and inconsistent regulatory frameworks and obligations issued by the Department of Labor. Shortly after the Mine Act was passed, OSHA and MSHA entered into their own self-imposed mandate, consistent with this congressional intent, in order to avoid just such regulatory conflict. In 1979, the agencies executed a Memorandum of Understanding (the "MOU" or the "Memorandum") to ensure the smooth and compatible operation of the agencies. *See Interagency Agreement between the Mine Safety and Health Administration, U.S. Department of Labor and the Occupational Safety and Health Administration, U. S. Department of Labor (March 29, 1979) September 11, 2023 10.50AM) https://www.msha.gov/msha-and-osha-memorandum*. MOU Section D(2) provides, "MSHA and OSHA will endeavor to develop compatible safety and health standards, regulations, and policies with respect to the mutual goals of the two organizations including joint rulemaking, where appropriate." *Id. at §D(2)* A central purpose of this provision of the MOU is to avoid precisely the situation that will be created if MSHA includes sorptive clays in its final revised silica

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that there is "considerable evidence" to support the presumption that the surface characteristics of silica (not present in ancient occluded quartz) are "important in producing disease" and the environmental influences available in the sorptive clay matrix can "change the toxicity of respirable crystalline silica," yet the agency finds that this information is insufficient to determine how these factors affect risk in any quantitative way. However, MSHA has no quantitative alternative theory or science against which this compelling toxicology does not measure up.

[15] OSHA did not come to its decision to exempt sorptive clays lightly or hurriedly; the agency proposed to include sorptive clays initially, but after careful evaluation of the body of scientific work and consensus understanding of the unique nature of occluded quartz in sorptive clays, it decided to exempt the material from coverage under its final standard. In excluding sorptive clays from coverage under its revised silica standard, OSHA stated, "[h]aving considered the evidence SMI submitted to the record, OSHA finds that although quartz originating from bentonite deposits exhibits some biological activity, it is clear that it is considerably less toxic than unoccluded quartz." 81 Fed. Reg. 16377 (March 25, 2016).

standard.

The Mine Act's statutory mandate and DOL's MOU attempting to ensure compatible health and safety standards from its agencies makes eminent sense not only from a policy standpoint, but from a practical standpoint. To do otherwise would create a non-sensical and logistical quagmire, where the industry's facilities could literally be subject to two differing permissible exposure limits: MSHA's PEL of 50 ug/m3 and OSHA's counterpart PEL of 100 ug/m3. Thus, the safety compliance personnel in this industry would need to establish two different industrial hygiene monitoring regimes with differing concentration limits, and MSHA safety inspectors and OSHA compliance officers would establish entirely inconsistent enforcement standards for the same company.

By rendering MSHA's final silica standard consistent with OSHA's as it applies to the sorptive minerals industry, MSHA would avoid rulemaking conducted in a manner "otherwise not in accordance with law." To do otherwise, a reviewing court may well "hold unlawful and set aside" the agency's actions pursuant to the Mine Act and the APA.

V. Conclusion

It is important to SMI and its membership to clarify their intent in submitting these Comments. SMI is not attempting to manufacture unfounded doubt, nor is it attempting to unnecessarily delay regulation of any substance that warrants regulation to ensure worker protection. We ask MSHA to accept that these Comments are submitted in full good faith, and with an objective of providing the Agency with the best available science to allow MSHA to update the research that it seems to have not evaluated in preparing its Proposed Rule. The vast majority of scientific research in the field has been conducted by objective, expert scientists and academic researchers with no affiliation whatsoever to SMI or its member companies or this industry generally. The integrity of SMI in its effort to continue to identify, compile, and encourage objective research in this area, regardless of outcome, is untarnished.

SMI is committed to ensure its workers are adequately protected. With over 80 years of operation without one known instance of silicosis among the industry's historic or current workforce, the industry has legitimate scientific and legal questions and concerns about MSHA's preliminary determination that occluded quartz ought to be regulated in the same manner as other species of quartz and other forms of crystalline silica. SMI strongly believes MSHA's preliminary decision warrants careful reexamination as, respectfully, we believe it is neither scientifically meritorious or legally valid.

SMI appreciates the opportunity to participate in MSHA's public comment process on the crystalline silica rulemaking, and encourages MSHA to review its Comments and the referenced scientific materials thoroughly as it develops its final silica standard.

Sincerely,

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