Commander Jessilynn B. Taylor Division of Toxicology and Human Health Services Agency for Toxic Substances and Disease Registry 1600 Clifton Road, NE, Mail Stop F-57 Atlanta, GA 30333

RE: *Federal Register* Notice 2015-02548 (Feb. 12, 2015): Notice of Intent to Develop Set 28 Toxicological Profiles

Dear Commander Taylor:

The Synthetic Amorphous Silica and Silicate Industry Association (SASSI) is a nonprofit organization incorporated in the District of Columbia as a 501(c)(6) entity on July18, 2007 by eight founding members. Key tenets of SASSI's mission focus on furthering the understanding of synthetic amorphous silica and silicate health and safety data within the industry, monitoring the regulation of synthetic amorphous silica and silicate by government, educating the public and government on the views of the industry, and consulting and cooperating with officials and agencies on matters having an industry-wide significance.

Consistent with our mission, the members of SASSI would like to take this opportunity to inquire about the February 12, 2015 *Federal Register* notice regarding the development of a toxicological profile on **Silica CASRN 7631-86-9** and to be assured that the Profile will be focused on crystalline forms of silica (CASRNs 14464-46-1/14808-60-7/15468-32-3) and not synthetic amorphous silica(SAS). We assume silica (7631-86-9) was included as one of the 275 hazardous substances on the Priority List of Hazardous Substances on the basis of the well-documented human health concerns related to crystalline silica. We believe it is imperative that ATSDR clearly identify the polymorphs of concern (crystalline forms) in its Profile, and clearly and explicitly excludes the SAS polymorphs.

Silica (including the crystalline polymorph), independent of its form and method of preparation (including by-products), is found under CAS No. 7631-86-9. To differentiate between the silica polymorphs, new polymorph-related CAS registry numbers have been generated (Figure 1). As the polymorphs of silica differ in their hazards to human health, it is essential to distinguish carefully between crystalline silica and non-crystalline or amorphous silica forms. Natural forms of amorphous silica like diatomaceous earth, especially flux-calcined diatomaceous earth, and amorphous silica fume – a by-product of silicon (Si) metal and ferrosilicon alloy manufacturing – may contain impurities, particularly crystalline silica.

We would like to refer ATSDR to the attached publication for a clear understanding of the SAS polymorphs and as a reference to the relevant toxicological properties of these materials: *European Centre for Ecotoxicology and Toxicology of Chemicals (ECOTOC)*

Joint Assessment of Commodity Chemicals No. 51 on "Synthetic Amorphous Silica (CAS No. 7631-86-9)

We appreciate your consideration of our comments and concerns. We are open to meeting with you and discussing any opportunity to assist ATSDR in completing a comprehensive and accurate review of Silica/SAS.

We look forward to your confirmation on the target silica polymorphs of the Profile.

Please contact me to determine how we can support the efforts of your organization.

Sincerely yours,

David A. Pavlich

Association Manager

Synthetic Amorphous Silica and Silicate Industry

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SASSI Member Companies:

- J.M. Huber Corporation
- Evonik Corporation
- Wacker Chemical Corp.
- Cabot Corporation
- Solvay
- PPG Industries, Inc.
- PO Corp.
- W.R. Grace & Co.

SASSI Website: www.sassiassociation.org