



Synthetic Amorphous Silica
and Silicate Industry Association

May 31, 2015

Comments from the
Synthetic Amorphous Silica and Silicate Industry Association
To
ACGIH on NIC on TLV of Calcium Silicate

The Synthetic Amorphous Silica and Silicate Industry Association (SASSI) is a national trade association. 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, and on behalf of our members, SASSI submits the following, additional comments to the Threshold Limit Values for Chemical Substances Committee for its upcoming review of Calcium silicate, synthetic nonfibrous as outlined in the January 30, 2015 letter to SASSI.

A. Executive Summary:

SASSI respectfully requests clarification on the notification that "The ACGIH Board of Directors voted to place Calcium silicate, synthetic nonfibrous on the 2015 NIC with a proposal to withdraw the currently adopted recommendation of a TLV-TWA of 10 mg/m³, containing no asbestos and <1% crystalline silica with an A4 carcinogenicity notation referring one to Appendix B: Particles Not Otherwise Specified of the *TLV and BEI* book." In particular we are interested in understanding the basis for selection of the A4 notation.

B. List of Recommendations:

According to the "CATEGORIES FOR CARCINOGENICITY BY THE AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS : **A4 Not classifiable as a human carcinogen:** Agents which cause concern that they could be carcinogenic for humans but which cannot be assessed conclusively because of a lack of data. In vitro or animals studies do not provide indications of carcinogenicity which are sufficient to classify the agent into one of the other categories."

SASSI believes there is sufficient data available to support an A5 classification: "**Not suspected as a human carcinogen:** The agent is not suspected to be a human carcinogen on the basis of properly conducted epidemiologic studies in humans. These studies have sufficiently long follow-up, reliable exposure histories, sufficiently high dose, and

adequate statistical power to conclude that exposure to the agent does not convey a significant risk of cancer to humans; or, the evidence suggesting a lack of carcinogenicity in experimental animals is supported by mechanistic data.”

SASSI recommends maintaining the current TLV for Calcium Silicate, synthetic non-fibrous at 10 mg/m³ (inhalable).

C. Rationale:

The health effects of SAS have been reviewed in recent years under a number of regulatory and voluntary programs, and all the available data on worker populations and animal studies support the fact that SAS is a non-toxic substance with characteristic health impacts that are similar to other low-toxicity, biologically inert dusts.

Industrial hygiene practices regarding the control and handling of SAS are grounded in over 60 years of manufacture and use, and collected exposure data and worker experience do not indicate any adverse worker health impacts.

D. Citable Material:

At this time, SASSI would again refer ACGIH to the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) Joint Assembly of Commodity Chemicals (JACC) Report #51(cited in SASSI's July 29, 2010 comment letter to ACGIH).

Additionally, as we noted in our July 29, 2010 comment letter, we believe there exists a rich scientific profile of the safety of amorphous silica and that the amorphous particle has been repeatedly shown to NOT share any of the health effects of crystalline silica. We reiterate that the rationale has recently been validated by the European Chemicals Agency (ECHA) in the acceptance of the registration dossier for calcium silicate under REACH. That dossier utilized data on synthetic amorphous silica as the primary basis for establishing a health effects classification. Calcium Silicate was considered non-hazardous. (Reference to the ECHA/REACH information is available on request.)

We appreciate the Committee's consideration of SASSI's comments and concerns. We are open to meeting with you and discussing any opportunity to assist ACGIH in completing a comprehensive and accurate review of synthetic calcium silicate.

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

SASSI Member Companies:

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

SASSI Website: www.sassiassociation.org