Synthetic Amorphous Silica
and Silicate Industry Association

Cosmetic Ingredient Review
1620 L St. N. W. Suite 1200
Washington D. C. 20036

May 31, 2019

Dr. Bart Heldreth, Ph.D., Executive Director, CIR

Comments from the
Synthetic Amorphous Silica and Silicate Industry Association
To
Cosmetic Ingredient Review
Dr. Bart Heldreth, Director and the Expert Panel
on
Amended Safety Assessment of Silica and Synthetically-Manufactured Silicates

as Used in Cosmetics: Draft Tentative Amended Report for Panel Review

Dear Dr. Heldreth,

In response to the Expert Panel's May 10, 2019 issuance of the "Draft Tentative Amended Report for Panel Review" the members of the Synthetic Amorphous Silica and Silicate Industry Association (SASSI) would like to take this opportunity to provide comments on the approach taken by the Expert Panel on the reassessment of the *CIR 2009 Final Report on the Safety Assessment of Silica and Related Cosmetic Ingredients*.

As noted in our correspondence of March 11, 2019, several members of SASSI responded to the Expert Panel's December 7, 2018 "Insufficient Data Announcement on Silica and Silicates" and provided substantial relevant particle size data on silica and silicate products used in cosmetic applications. Although the Expert Panel characterized this summary as no new information ("Because I don't think there's any really new information. They sent us a data dump is what it appeared to be, with some particle size characterizations, which is helpful. But I don't know that there's any new information in there whatsoever"), we believe the data more than adequately fulfilled the specific requirements of the IDA but if it does not please describe the information still needed.

We concur with the Panel members' concern that once a manufacturer of an ingredient sends it to the formulator, then it is the formulator's obligation to figure out what happens to the ingredients during processing. The level of concern should be specific to each ingredient. We maintain that the inhalation toxicity and epidemiology study results previously reviewed by the Panel indicate that inhalation exposure level from cosmetic products will be substantially below the levels investigated in these reports, which resulted in multiple findings that SAS is "essentially non-toxic", and which were relied upon by Panel members in acknowledging that synthetic amorphous silica is not an issue with inhalation and is not a respiratory toxin.

We also noted in the transcript from the April 2019 meeting several Panel member comments indicating confusion about crystalline silica versus synthetic amorphous silica. We are concerned that this remains a point of confusion for the Panel. The 2009 Report clearly articulated that only synthetic amorphous silica ingredients are authorized for use in cosmetic formulations. We must continue to be vigilant about requiring clear differentiation between synthetic amorphous silica and crystalline silica health hazards, thus we are again concerned about possible confusion over the results of the assessment unless this point is sufficiently explicit in any subsequent report.

Also as noted in the transcript from the April 2019 meeting, although it is not clear why the 2009 Report was not published, the Expert Panel's decision to combine it with a number of other reports and to also add a substantial number of new ingredients has raised many concerns (including panel members) about the structure and form of the report, with specific concerns about ingredients that are difficult to categorize and are lacking in safety data. Many of these materials have compositions and physico/chemico structures significantly different from SAS compounds and may not have the same safety profiles. We believe these materials warrant separate assessments in order to satisfy the systematic safety issue evaluation outlined by the Panel in April.

Regarding the reassessment of the materials in the 2009 report, we believe the detailed data set provided for these products substantiated that these materials are "essentially non-toxic." (ref: JACC 51: Executive Summary: "In humans, SAS is essentially non-toxic by mouth, skin or eyes, and by inhalation. Epidemiology studies show little evidence of adverse health effects due to SAS. Repeated exposure (without personal protection) may cause mechanical irritation of the eye and drying/cracking of the skin.")

In addition to the references we have provided in the past, we would refer the Expert Panel to the following:

(1) Morfeld, P. et al. 2014. *Cross-sectional study on respiratory morbidity in workers after exposure to synthetic amorphous silica at five German production plants: exposure assessment and exposure estimates*. J. Occup. Environ. Med. 2014 Jan, 56(1); 72-78

(2) Taeger D, McCunney R, Bailer U, Barthel K, Küpper U, Brüning T, Morfeld P, Merget R. *Cross-sectional study on nonmalignant respiratory morbidity due to exposure to synthetic amorphous silica*. J. Occup. Environ. Med. 2016

(3) Fruijtier-Pölloth, C *The toxicological mode of action and the safety of synthetic amorphous silica—A nanostructured material.* Toxicology 294 (2012) 61– 79

The more recent overview by Fruijtier-Pölloth reiterates the position that "none of the recent available data gives any evidence for a novel, hitherto unknown mechanism of toxicity that may raise concerns with regard to human health or environmental risks."

In conclusion, we suggest another approach: updating the 2009 Report (and hopefully publishing it) and dealing with the disparate list of other ingredients separately.

We are open to discussing any opportunity to assist CIR in completing a comprehensive and accurate review of synthetic amorphous silica and silicate ingredients. Please contact me to determine how we can support the efforts of your organization.

We look forward to your response.

Sincerely yours,

David A. Pavlich

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