



Cosmetic Ingredient Review  
1101 17th Street, NW, Suite 412  
Washington, DC 20036

February 24, 2011

Dr. F. Alan Andersen, Director

Dear Dr. Andersen:

The Synthetic Amorphous Silica and Silicate Industry (SASSI) Association has reviewed the Scientific Literature Review issued by CIR on December 20, 2010 for “Silica Silylate, Silica Dimethyl Silylate, Trimethylsiloxysilicate and Trifluoropropyldimethyl/Trimethylsiloxysilicate (as used in Cosmetics)”, and would like to offer the following comments for consideration prior to the issuance of the Preliminary Safety Report.

General comments:

- 1) It is unclear which surface-treated silicas are meant to be included in this review. Most of the toxicity data evaluated are for silica dimethyl silylate. Yet HMDS-treated silica is mentioned on page 2 (see Method of Manufacture) and is listed as silica silylate, yet no silica silylate studies are provided. In addition, we notice that PDMS-treated silica is listed under Table 1 (CAS 67762-90-7), yet only one of the Cabot studies we provided for this product is listed in the report (Ref. 53, Table 5 for silica dimethyl silylate). All of the available data for the PDMS-treated products should be included in the report. The toxicity studies for HMDS- and PDMS-treated silicas have been summarized for all of the manufacturers' products in detail in the ECETOC JACC Report No. 51 – Synthetic Amorphous Silica, 2006, which was previously submitted to CIR.
- 2) In general, the summary seems to be missing physical/chemical information (including chemical structures for silica dimethyl silylates), toxicity, and use data for several of the substances evaluated in this report. There is no introduction before the Toxicokinetics and Toxicology sections indicating what data were available at the time of writing.

Specific comments:

- 1) Introduction, paragraph 3: “silica” should be referred to here as “Synthetic amorphous silica” initially and then state that it is thereafter referred to as “silica”.
- 2) Introduction, paragraph 4: CAB-O-SIL® TS-720 should be referred to as siloxanes and silicones, dimethyl, reaction product with silica not “treated fumed silica dust”.
- 3) Introduction, paragraph 4: the Antifoam A is 93% PDMS (the treating agent). These data are not relevant to the surface treated silicas described in this report.

The formulation of Antifoam M is not listed here but appears to be treating agent only without the attached particles.

- 4) Chemistry, paragraph 2: “Grafted” should be replaced with “Surface-modified”.
- 5) Physical and Chemical properties: This section could be improved by referencing properties from the JACC report mentioned above. The missing properties for silica silylate can be found on the MSDS in the JACC report (Chapter 2) as well.
- 6) Method of Manufacture: As mentioned above, HMDS-treated silica is mentioned here yet no data are provided in the report.
- 7) Use, paragraph 1: “There were no uses...(in cosmetic applications)”, why include materials in the review? Also, spelling error in second line of “Non-Cosmetic Use” paragraph.
- 8) Use, paragraph 2: “Most of the particles are >125 um and none were < 90 um. Therefore, effects on the lungs that may be induced by aerosolized products containing these ingredients are of concern” is not correct and contradicts what is stated in the paragraphs that follow. At those sizes, the particles would be trapped in the nasopharyngeal area and would not enter the lungs.
- 9) Toxicokinetics: These Antifoam studies do not seem relevant as mentioned earlier. In addition, the references for these two studies are not listed.
- 10) Toxicokinetics: Additional information on sensitization-Effects on Humans: Approximately 50 years of experience of exposed workers gave no evidence of skin sensitization or allergic contact dermatitis. The only signs seen on worker`s skin were signs of irritation due to the dessicative and defatting property of SAS, which resulted in skin dryness. This adverse effect was reversible and could be controlled by regular use of skin protection ointment (ref: ECETOC JACC report No. 51, 2006)
- 11) Toxicological Studies, Acute Toxicity, Inhalation – Non-Human: “There were no mortality up to 520 mg/m<sup>3</sup>” contradicts the summary on Page 7 which states that mortality was observed at 209 mg/m<sup>3</sup>. It should be noted that the exposure conditions in the animal inhalation studies are not relevant to workplace exposure since the particles undergo high shear forces in the laboratory in order to generate particles small enough to be of respirable size to the animals. Hence, these studies are not useful for risk assessment purposes. This is also true for the repeated dose studies in animals and a similar statement should be added there as well.
- 12) Toxicology, Repeated Dose, Inhalation – Non-Human: Inhalation studies are presented in Table 5 not Table 4.
- 13) Genotoxicity, In vitro (last paragraph): The reference (#37) for the chromosome aberration study is linked with the incorrect study – it is linked with the Ames test mentioned above, not the chromosome aberration test.
- 14) Irritation, Ocular, Non-Human (last paragraph): The reference for this study is missing.
- 15) Summary, paragraph 1: The summary states that it is a scientific literature review for 4 products but make no mention of the fact that there are no data in the report for most of the products. Further, no overall conclusion was made. This should be done once all of the data have been received/added.

- 16) Table 1: CAS # 68909-20-6 should be included under Silica silylate as described at the top of page 2. CAS # 63142-62-9 is for the PDMS treating agent not the treated particle and should be removed from silica dimethyl silylate. Also, “treated fumed silica dust” is not a correct product name for CAB-O-SIL® TS-720 and should be removed. (See: Specific Comment #2 above).  
Also to Table 1 the following CAS numbers and identifiers should be included:

Silica Silylate:

RN 68909-20-6

- CN Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (TSCA, DSL, REACH, EINECS, AICS, PICCS, ASIA-PAC, NZIoC)  
Bis(trimethylsilyl)amine, produits d'hydrolyse avec la silice (French) (DSL)  
silanamine, trimethyl-1,1,1 N-(trimethylsilyl)-, produits d'hydrolyse avec la silice (French) (EINECS)  
Silanamin, 1,1,1-Trimethyl-N-(trimethylsilyl)-, Hydrolyseprodukte mit Siliciumdioxid (German) (EINECS)  
silanamina, 1,1,1-trimetil-N-(trimetilsilil)-, productos de hidrolisis con silice (Spanish) (EINECS)  
1,1,1-Trimethyl-N-(trimethylsilyl)silanamine hydrolysis products with silica (ECL)  
HYDROLYSIS PRODUCTS WITH SILICA, SILANAMINE,  
1,1,1-TRIMETHYL-N-(TRIMETHYLSILYL)- (PICCS)  
Hexamethyldisilazane, silica reaction product

Trimethylsiloxysilicate:

RN 104133-09-7

- CN Silicic acid (H<sub>4</sub>SiO<sub>4</sub>), tetraethyl ester, polymer with hexamethyldisiloxane (AICS, PICCS, ASIA-PAC)

- 17) Table 2: Cabot's trade names are not listed in this table. Please add CAB-O-SIL® TS-530 to the silica silylate trade names, and add CAB-O-SIL® TS-610 and CAB-O-SIL® TS-720 to the silica dimethyl silylate trade names.  
18) Table 3: The density of CAB-O-SIL® TS-610 (silica dimethyl silylate) is 1.8 - 2.2 g/cm<sup>3</sup> @ 20°C.

Additional reference material: SASSI will provide an electronic copy of the following studies/reports:

- 1) “Some Results of Dissolution Experiments Carried Out with Different Kinds of Amorphous Silica” Vogelsberger, Wolfram; Friedrich-Schiller-Universitat
- 2) “Guidance for handling and use of nanomaterials at the workplace”, Heinemann, M., Schafer, H.G; Human and Experimental Toxicology(2009) 28: 407-411.

As I mentioned in our previous letter, we are open to discussing any opportunity to assist CIR in completing a comprehensive and accurate review of treated synthetic amorphous silica. Please contact me if the Expert Panel has any questions about our comments or to determine how we can further support the efforts of your organization.

We look forward to continuing our communication with your organization.

Sincerely yours,

A handwritten signature in black ink that reads "David A. Pavlich". The signature is written in a cursive style with a large, looping initial 'D'.

David A. Pavlich  
Association Manager  
Synthetic Amorphous Silica and Silicate Industry