



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

August 31, 2011

Dr. F. Alan Andersen, Director

Dear Dr. Andersen:

The Synthetic Amorphous Silica and Silicate Industry (SASSI) Association has reviewed the Tentative Safety Assessment (TSA) issued by CIR on July 6, 2011 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 Final Safety Report.

General comments:

- 1) As we discussed on August 16th, our February 24, 2011 letter to CIR (and the reference documents also provided at the same time) were not made available for review and consideration by the Expert Panel prior to the March 3-4 meeting or prior to the issuance of the July 7, 2011 TSA. It is imperative that before the publication of the Final Safety Report, a number of the key points we addressed in our letter need to be taken into consideration in light of the conclusions and recommendations in the TSA. We specifically refer the Expert Panel to “Specific comments 8, 9, 10, 11, and 12” in our February 24 letter and to the toxicity studies for HMDS- and PDMS-treated silicas 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) Based on information that has been made available, we disagree with the Expert Panel’s assessment “that no inhalation toxicity data were available.”
- 3) Based on information that has been made available, we consider as not relevant the studies referenced by the Expert Panel in forming their conclusion that “Inhalation data show that the particles do reach the lungs in rats and induce granulomata formation. There is also necrosis or atrophy of the olfactory epithelium observed. There are currently no data available on which to base a finding of safe for use in products which may be inhaled.”
- 4) Based on information that has been made available and the recommendations of CIR in Safety Assessment of Silica and Related Cosmetic Ingredients (Sept. 25, 2009), we do not believe the recommendation for a “13-week inhalation toxicity study that evaluates both the nasopharyngeal cavity and the lung, using the smallest particle size available for use in cosmetics” is warranted.

Specific comments:

- 1) For General Comments 2, 3 & 4: The ECETOC JACC No. 51 report includes surface-treated SAS, including Silica Silylate (treated with hexamethyldisilazane), Silica Dimethyl Silate (treated with dimethyldichlorosilane) and Silica Dimethicone Silylate (treated with polydimethylsiloxane). The report states: “The surface treatment does not change the solid properties e.g. particle size, dissolution kinetics of the inorganic polymer silicon dioxide (silica, SiO<sub>2</sub>). However, surface treatment does alter the physico-chemical properties, e.g. reduced moisture uptake.” In the summary of the toxicological testing (Chapter 8 of the ECETOC report), information on surface-treated SAS is summarized under “hydrophobic SAS”.
- 2) In response to General Comment 3, reference 60 is not relevant because the material causing the effects of concern contained crystalline silica (quartz).
- 1) In response to General Comment 4: With respect to particle size distribution see page 7 of “Safety Assessment of Silica and Related Cosmetic Ingredients (CIR: Sept. 25, 2009)”: “**Particle Size and Form: Silica:** Amorphous Silicas are composed of very fine particles (average of 20 µm) which tend to aggregate loosely in the air (Byers and Gage 1961). Primary particles, or single particles, do not exist in isolation in fumed (pyrogenic) and precipitated silica; only in silica sol (colloidal). Aggregates assemble in chains (fumed) or clusters (precipitated and gel). Agglomerates are assemblies of aggregates, held together by strong physical adhesion forces and not in a dispersible nano size (< 100 nm) (ECETOC 2006; Gray and Muranko 2006).” As reference above, “surface treatment does not change the solid properties e.g. particle size...”

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,



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