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Official report

Opinion of the Scientific Committee on Consumer Safety (SCCS) – Revision of the opinion on the safety of the use of Silica, Hydrated Silica, and Silica Surface Modified with Alkyl Silylates (nano form) in cosmetic products

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ABSTRACT

Conclusion of the opinion: The SCCS has concluded that the evidence, both provided in the submission and that available in scientific literature, is inadequate and insufficient to allow drawing any firm conclusion either for or against the safety of any of the individual SAS material, or any of the SAS categories that are intended for use in cosmetic products.
As the SCCS has not been able to conclude on the safety of the synthetic amorphous silica (SAS) materials included in the current submission, the Applicant is advised to follow the SCCS Guidance on Risk Assessment of Nanomaterials (SCCS/1484/12).
A brief summary is provided to enable/facilitate future evaluation of the SAS materials in cosmetic products.

Opinion to be cited as: SCCS (Scientific Committee on Consumer Safety), Opinion on Silica, Hydrated Silica, and Silica Surface Modified with Alkyl Silylates (nano form) 20 March 2015, revision of 29 September 2015, SCCS/1545/15.

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Link to the SCCS Opinion:
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_175.pdf.

Article 2(1) (k) of Regulation (EC) No 1223/2009 establishes that "nanomaterial" means an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.

That definition covers only materials in the nano-scale that are intentionally made and are insoluble/partially-soluble or biopersistent (e.g. metals, metal oxides, carbon materials, etc), and it does not cover those that are soluble or degradable/non-persistent in biological systems (e.g. liposomes, emulsions, etc). Article 16 of the Cosmetics Regulation requires any cosmetic product containing nanomaterials to be notified to the Commission six months prior to being placed on the market, and Article 19 requires nano-scale ingredients to be labelled (name of the ingredient, followed by 'nano' in brackets). If there are concerns over the safety of a nanomaterial, the Commission shall refer it to the Scientific

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Committee on Consumer Safety (SCCS) for a full risk assessment.

The Commission received 172 notifications as reported in the attached list of cosmetic products containing the following nanomaterials: 67 notifications for Silica (nano) CAS n.l 12945-52-5; 26 notifications for the Hydrated Silica (nano) CAS n. 112926-00-8; 12 notifications for Silica Silylate (nano) CAS n. 68909-20-6; 67 notifications for Silica Dimethyl silylate (nano) CAS n. 68611-44-9. These ingredients are not regulated in Cosmetic Regulation (EC) No 1223/2009, but they are reported in the Cosing database with several cosmetic functions. According to the Applicant the ingredients are used in nano form in leave-on and rinse-off cosmetics products, including hair, skin, lip, face, and nail products, with different concentrations and specifications as reported.

The Commission had concerns about the use of silica in nano form because of the potential high exposure in many types of products and because concerns have been raised regarding the potential for nanoparticles of silica to break out of the agglomerates and enter cells.

Therefore, the SCCS was requested to provide a safety assessment of the four types of nano silica covered in the notifications, in the above-mentioned categories of products, taking into account the reasonably foreseeable exposure conditions.

The submission comprises safety assessment of 28 SAS materials, of which the SCCS has considered 23 materials relevant for this opinion (Table 1). These materials could be categorised into four categories: hydrophilic precipitated silica; hydrophilic pyrogenic silica; hydrophobic pyrogenic silica, and colloidal silica materials.

The physicochemical and safety data provided for the materials under consideration have been regarded by the Applicant as representative for the different types of SAS materials intended for use in cosmetic products. However, the SCCS evaluation has shown that, even within an SAS category, different materials have large differences in the experimental values for some of the physicochemical properties (section 3.1.9). No justification has been provided to explain such large variations. CAS/EC numbers for hydrophobic and hydrophilic materials are also different, suggesting that they are indeed different materials. In the absence of further justification for read-across, this has not allowed the SCCS to use data from one material to another, either within a given SAS category or between different categories. The SCCS has therefore used a case-by-case approach to assess each material against the physicochemical and toxicological safety data provided for that particular material. In doing so, the SCCS has identified a number of inadequacies and gaps in the data relating to physicochemical properties, toxicological data and exposure assessment – i.e. in all three elements essentially required for risk assessment (see Annex-Table 1 and section 3.3.14). This is despite the fact that these issues had already been pointed out to the Applicant by the SCCS in the preliminary comments on the original submission in 2014.

After detailed evaluation of the current submission, the SCCS has concluded that the evidence, both provided in the submission and that available in scientific literature, is inadequate and insufficient to allow drawing any firm conclusion either for or against the safety of any of the individual SAS material, or any of the SAS categories, that are intended for use in cosmetic products.

As the SCCS has not been able to conclude on the safety of the SAS materials included in the current submission, the Applicant is advised to follow the SCCS Notes of Guidance (SCCS/1501/12), the SCCS Guidance on Risk Assessment of Nanomaterials (SCCS/1484/12), and the SCCS Memorandum on Data Quality (SCCS/1524/13) for any future evaluation of the SAS materials.

As mentioned before, if the SCCS opinion is to be sought again for more than one material in a single submission, a scientifically valid reasoning would be required to justify a 'readacross' between different materials/categories. In the absence of such a justification, the SCCS will use a case-by-case approach, which will inevitably require adequate data on each individual material under evaluation.

From the current evaluation, the SCCS has noted a number of inadequacies and data gaps.

Whilst more detailed analysis of these is presented in relevant sections (e.g. see Annex-Table 1 and section 3.3.14), the following brief summary is provided to enable/facilitate future evaluation of the SAS materials in cosmetic products:

- Adequate dermal absorption data would be of paramount importance for safety assessment of all types of SAS materials intended for use in cosmetic products.
  - o For neat (i.e. not surface-treated) SAS materials, that are produced by a pyrogenic process and have physicochemical profile(s) similar to those used for food applications, adequate physicochemical characterisation and dermal absorption data would be particularly important for the SCCS evaluation.
  - o For surface modified (hydrophobic) SAS materials, a clear identification of the surface moieties on each SAS material should also be provided; and the dermal absorption data should cover each type of the surface modification used;
  - o If any of the SAS materials is intended for use in ethanolic formulation for cosmetic applications, the penetration potential of the nanoparticles should also be assessed in ethanolic media.
- For the SAS materials produced by a non-pyrogenic route (e.g. precipitation), additional data on secondary particle size should be provided to clearly indicate whether the primary particles are in aggregated as well as agglomerated form, or just in agglomerated form, as the latter could de-agglomerate under certain conditions to give off nanoparticles;
- When using data in support of an SAS category, scientific reasoning should be provided to explain any large variation in the physicochemical properties for the materials within the category;
- In toxicological tests, it is often indispensable to show the associated toxicokinetics *in vitro*, e.g. in genotoxicity/mutagenicity tests, as an evidence of the materials coming into contact with the target tissues/cell to validate the negative results.
- For all types of SAS, data on particle size distribution should be provided from a method other than DLS.
- The material examples/categories provided with physicochemical characterisation and those provided with toxicity data should be overlapping.

Data from appropriately designed studies are needed to exclude the toxicity of the SAS materials, in particular the mutagenic/genotoxic potential, considering the different possible exposure routes, the SAS concentration, and actual use conditions of the final products.

Further studies are also needed to exclude the possibility of dermal penetration of SAS materials, especially the surface modified hydrophobic types, in the media/formulations that are relevant to the final product.

Reference:

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_175.pdf

Transparency document

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