

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion: Silica (nano) CAS n.112945-52-5; Hydrated Silica(nano) CAS n. 112926-00-8; Silica Sylilate CAS n. 68909-20-6; Silica Dimethyl silylate (nano) CAS n. 68611-44-9

1. Background

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 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.112945-52-5; 26 notifications for the Hydrated Silica (nano) CAS n. 112926-00-8; 12 notifications for Silica Sylilate (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 in the attached list.

The Commission has concerns on 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, we would like to request the SCCS a safety assessment of the four types of nano silica covered in the notifications listed in the annex to this mandate, in the above-mentioned categories of products, taking into account the reasonably foreseeable exposure conditions.

2. Terms of reference

1. *In view of above, and taken into account the scientific data provided, SCCS is requested to give its opinion on the safety of the nanomaterials Silica, Hydrated*

Silica, Silica Silylate and Silica Dimethyl Silylate for use in leave-on and rinse-off cosmetics products, including hair, skin, lip, face, and nail products, taking into account the reasonably foreseeable exposure conditions.

2. *In the event the SCCS finds that the safety assessment for one or more of the nanomaterials covered by this mandate should be provided in a separate opinion, the SCCS is asked to justify its the decision.*
3. *SCCS is requested to address any further scientific concerns with regard to the use of Silica, Hydrated Silica, Silica Silylate and Silica Dimethyl silylate in nano form in cosmetic products.*

3. Deadline: six months from reception

4. Supporting documents

List of notifications of cosmetic products containing Silica, Hydrated Silica, Silica Silylate and Silica Dimethyl silylate in nano form received through the Cosmetic Products Notification Portal