

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion: Colloidal Silver (nano) CAS No 7440-22-4,
EC No 231-131-3

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 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 63 notifications of cosmetic products containing Colloidal Silver (CAS No 7440-22-4, EC No 231-131-3) in nano form, as reported in the attached list. This ingredient is reported in the CosIng database without any reference to the nano form with the function of abrasive, bulking and emulsion stabilising, but it is not regulated in Cosmetic Regulation (EC) No 1223/2009. According to the applicants, the ingredient is used in nano uncoated form both in leave-on and rinse-off oral cosmetics products including toothpastes and skin care products with maximum reported concentration limit of 1 % and specifications as reported in the attached list.

The Commission has concerns over safety of the use of Colloidal Silver in nano form in cosmetic products.

The Commission published a 12 weeks call for data with deadline 30 June 2015 where interested parties were invited to submit any relevant scientific information on the safety of Colloidal Silver (CAS No 7440-22-4, EC No 231-131-3) in nano form used in cosmetic products and in particular data regarding all toxicological end-points and an indication on the suggested concentration safe limits for this ingredient. The documentation received by Commission is in the annex to this mandate.

Therefore, the Commission is requesting the SCCS a safety assessment of the nano form of Colloidal Silver 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, the SCCS is requested to give its opinion on the safety of the nanomaterial Colloidal Silver when used in cosmetics including toothpastes and skin care products with a maximum concentration limit of 1 %, taking into account the reasonably foreseeable exposure conditions.*
2. *SCCS is requested to address any further scientific concerns with regard to the use of Colloidal Silver in nano form in cosmetic products.*

3. **Deadline: six months from reception**

4. **Supporting documents**

- List of notifications of cosmetic products containing Colloidal Silver in nano form received through the Cosmetic Products Notification Portal.
- Call for Data on Colloidal Silver nano. European Commission DG GROW. 2015
- Submission to the Scientific Committee on Consumer Safety (SCCS) on the safety of "Colloidal Silver (nano)". Friends of Earth Australia/Germany 2015
- Bernd Nowack, Harald F. Krug, and Murray Height (2011) 120 Years of Nanosilver History: Implications for Policy Makers. *Environ. Sci. Technol.* 45, 1177–1183
- SNWG Comments on Colloidal (nano) Silver in Cosmetics. May 2015
- EPA Response to "Petition for Rulemaking Requesting EPA Regulate Nano-Silver Products as Pesticides". Unites States Environmental Agency. March 2015
- References Mr Vacca
- List of Publications Zip