

**CALL FOR DATA ON INGREDIENTS:
"COLLOIDAL SILVER (nano)"
IN THE FRAMEWORK OF REGULATION (EC) 1223/2009 OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL ON COSMETIC PRODUCTS**

Policy fields

Internal market and Industry, Public Health.

Target

Any interested parties, including authorities of the Member States, manufacturers of cosmetic products, producers of the substances concerned and relevant industry and consumers associations.

Period of consultation: from 25 March to 30 June 2015

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 Regulation (EC) No 1223/2009 (Cosmetics Regulation) requires any cosmetic product other than colorants, preservatives and UV-filters, containing nanomaterials to be notified to the Commission six months prior to being placed on the market. 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 has received the notification of several cosmetics products containing the ingredient "Colloidal silver (nano)" (CAS No 7440-22-4, EC No 231-131-3). This ingredient "Colloidal silver" as such is not regulated in Cosmetics Regulation, but it is reported in the CosIng database with antimicrobial functions. According to the applicants, the ingredient is used as antimicrobial in nano form with a lowest cut off particle size of 1 nm and at maximum concentration up to 1.0 % in cosmetic products.

Action proposed by the Commission

The Commission has concerns on the use of "Colloidal silver (nano)" because of the potential toxicity of its nanoparticles that enter into the cells and because the data submitted by the applicants seems to be insufficient to carry out a full risk assessment. The dossier shall be in line with the SCCS's Notes of Guidance for the

testing of cosmetic ingredients and their safety evaluation (8th revision)¹ and with SCCS Guidance on the safety assessment of nanomaterials in cosmetics².

In order to prepare requests for scientific opinions to the Scientific Committee on Consumer Safety (SCCS), interested parties are invited to submit any relevant scientific information on the safety of "Colloidal silver (nano)" (CAS No 7440-22-4, EC No 231-131-3) used in cosmetic products in particular data regarding all toxicological end-points and an indication on the suggested safe concentration limits for this ingredient.

Request

In view of the above, the Commission would like to invite any interested parties, including authorities of the Member States, manufacturers of cosmetic products, producers of "Colloidal silver (nano)", relevant industry and consumers associations, to submit their contribution.

How to submit your contribution

Any comments should be sent with the reference:

COLLOIDAL SILVER (nano)

by post or e-mail by 30 June at the latest to:

European Commission
Directorate General Internal Market, Industry, Entrepreneurship and SMEs
Unit/I4, Health Technology and Cosmetics,

Jean-André de Mot, Office 02/082
B-1049 Brussels,
Belgium

E-mail: grow-cosmetics-and-medical-devices@ec.europa.eu

Privacy statement

¹ http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_006.pdf

² http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_005.pdf