



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Resources Based, Manufacturing and Consumer Goods Industries
Health Technology and Cosmetics

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion on Hydroxyapatite (nano). CAS No 1306-06-5, EC No. 215-145-20.

Commission Department requesting the Opinion: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

1. Background

Article 2(1)(k) of Regulation (EC) No 1223/2009 (Cosmetics Regulation) states 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. some metals, metal oxides, carbon materials, etc.). 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 cosmetic products containing nanomaterials other than colorants, preservatives and UV-filters and not otherwise restricted by the Cosmetics Regulation to be notified to the Commission six months prior to being placed on the market. Article 19 of this Regulation 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 notified nanomaterial, according to Article 16 of the Regulation the Commission shall refer it to the Scientific Committee on Consumer Safety (SCCS) for a full risk assessment.

The Commission services received 17 notifications under Article 16 of the Cosmetics Regulation via the Cosmetic Product Notification Portal (CPNP) for cosmetic products containing Hydroxyapatite (CAS No 1306-06-17 and EC No. 215-145-20) in nano form, as reported in the attached list. Hydroxyapatite without any reference to the nano form is reported in the CosIng database as an abrasive, bulking, oral care and skin-conditioning agent. It is not regulated under the Cosmetic Regulation (EC) No 1223/2009.

According to the notifications submitted, this ingredient is used in both leave-on and rinse-off dermal and oral cosmetic products, including skin (skin care) and oral hygiene (toothpaste, mouthwash) products, with different concentration and specifications as reported in the attached list.

The Commission has concerns on the use of Hydroxyapatite in nano form because of the potential for nanoparticles to be absorbed dermally or across a mucous membrane and to enter cells. Therefore, we request the SCCS to carry out a safety assessment of the nano form of Hydroxyapatite reported in the notifications listed in the annex to this mandate.

2. Terms of reference

(1) In view of the above, and taking into account the scientific data provided, does the SCCS consider the nanomaterial Hydroxyapatite safe when used in leave-on and rinse-off dermal and oral cosmetic products according to the maximum concentrations and specifications reported in the attached list, taking into account reasonably foreseeable exposure conditions?

(2) Does the SCCS have any further scientific concerns with regard to the use of Hydroxyapatite in nano form in cosmetic products?

3. Deadline: six months from reception via the CPNP portal

The SCCS adopted this mandate at the SCCS plenary meeting on 20/21 June 2019.