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

Ecosystems I: Chemicals, food, retail
Unit F2: Bioeconomy, chemicals, cosmetics

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion on "Hydroxyapatite (nano)" (CAS/EC No.: 1306-06-5/215-145-7)

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.

The nanomaterials definition covers materials in the nano-scale that are intentionally made and are insoluble/partially-soluble or biopersistent. It does not cover those that are soluble or degradable/non-persistent in biological systems. 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, the Commission shall refer it to the Scientific Committee on Consumer Safety (SCCS) for a full risk assessment.

The Commission services received a number of 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. 215-145-7) in nano form. Hydroxyapatite 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.

In view of potential concerns to human safety, the Commission services mandated the SCCS on the safety of Hydroxyapatite (nano). In October 2015 and in December 2021, the SCCS having considered the data submitted via the CPNP, additional data requested from the Responsible Persons and other relevant information available in scientific literature, could not conclude on the safety of the Hydroxyapatite (nano) composed of rod–shaped nanoparticles for use in oral cosmetic products at the maximum concentrations and specifications reported. Furthermore, the SCCS stressed that the available data/information is not sufficient to exclude concerns over the genotoxic potential of Hydroxyapatite (nano).

In February 2022, industry submitted additional information to support the safety of Hydroxyapatite (nano) in oral products, specifically addressing the potential genotoxicity of Hydroxyapatite (nano).

2. Terms of reference

(1) In view of the above, and taking into account the scientific data provided, does the SCCS consider Hydroxyapatite (nano) safe when used in oral cosmetic products according to the maximum concentrations and specifications as reported in the submission, taking into account reasonably foreseeable exposure conditions?

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

3. Deadline: six months

4. Supporting documents

Safety dossier submission by Industry.