



EUROPEAN COMMISSION

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

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

Brussels,  
GROW/F/2/[REDACTED]  
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NOTE TO THE ATTENTION OF [REDACTED]  
[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]

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

This note requests the assistance of your unit for the safety evaluation by the Scientific Committee on Consumer Safety (SCCS) of the substance Hydroxyapatite (nano) (CAS No. 1306-06-5, EC No. 215-145-7) used in cosmetics products.

It would be appreciated if the request and submission summary are passed on to the appropriate specific working party within the SCCS for their safety review. The full data including all references of the submission has been delivered to the SCCS secretariat.

If the SCCS needs further information, our unit would be happy to provide it.

*(e-signed)*  
[REDACTED]

C.c.: [REDACTED]

## SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

**Request for a scientific opinion:** on Hydroxyapatite (nano) (CAS No. 1306-06-5, EC No. 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<sup>1</sup> and in December 2021<sup>2</sup>, the SCCS 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). In March 2023<sup>3</sup>, the SCCS concluded on the safety of Hydroxyapatite (nano) when used at concentrations up to 10 % in toothpaste, and up to 0.465 % in mouthwash, when Hydroxyapatite (nano) is composed of rod-shaped particles of which at least 95.8 % (in particle number) have an aspect ratio less than 3, and the remaining 4.2 % have an aspect ratio not exceeding 4.9 and the particles are not coated or surface modified.

Following a regulatory proposal by the Commission services to restrict the use of Hydroxyapatite (nano) in cosmetics, industry submitted evidence to demonstrate its safety at higher concentrations

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<sup>1</sup> SCCS (Scientific Committee on Consumer Safety), Opinion on hydroxyapatite (nano), 16 October 2015, SCCS/1566/15, revision of 16 March 2016.

<sup>2</sup> SCCS (Scientific Committee on Consumer Safety), Opinion on Hydroxyapatite (nano), preliminary version of 27-28 October 2020, final version of 30-31 March 2021, SCCS/1624/2020.

<sup>3</sup> SCCS (Scientific Committee on Consumer Safety), Opinion on Hydroxyapatite (nano), preliminary version 4 January 2023, final version 21-22 March 2023, SCCS/1648/22.

in oral products. The Commission, therefore, requests the SCCS to carry out a safety assessment on Hydroxyapatite (nano) in view of the new information provided.

## **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 toothpaste up to a maximum concentration of 29.5 % and in mouthwash up to a maximum concentration of 10 % according to the specifications as reported in the submission, taking into account reasonably foreseeable exposure conditions?*
- (2) *Alternatively, what is according to the SCCS the maximum concentration considered safe for use of Hydroxyapatite (nano) in cosmetic products?*
- (3) *Does the SCCS have any further scientific concerns with regard to the use of Hydroxyapatite (nano) in oral cosmetic products?*

## **3. Deadline**

9 months.

## **4. Supporting documents**

Safety dossier submission by Industry.