

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion: Hydroxyapatite (nano) CAS No 1306-06-5

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 26 notifications of cosmetic products containing Hydroxyapatite (CAS No 1306-06-5) 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, tooth whiteners and mouth washes with maximum reported concentration limit of 10% 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 of Hydroxyapatite to be absorbed and enter into the cells.

Therefore, we would like to request the SCCS a safety assessment of the nano form of Hydroxyapatite 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 Hydroxyapatite when used in oral cosmetics products including toothpastes, tooth whiteners and mouth washes with a maximum concentration limit of 10%, taking into account the reasonably foreseeable exposure conditions.*
- 2. SCCS is requested to address any further scientific concerns with regard to the use of Hydroxyapatite in nano form in cosmetic products.*

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

4. Supporting documents

List of notifications of cosmetic products containing Hydroxyapatite in nano form received through the Cosmetic Products Notification Portal.