Regulatory Toxicology and Pharmacology 98 (2018) 274–275

Contents lists available at ScienceDirect

Regulatory Toxicology and Pharmacology

journal homepage: www.elsevier.com/locate/yrtph

Opinion of the Scientific Committee on Consumer Safety (SCCS) – Revision of the Opinion on hydroxyapatite (nano) in cosmetic products

, Scientific Committee of Consumer Safety - SCCS[a,*], Ulrike Bernauer[b,1]

[a] SCCS Secretariat at the European Commission, Directorate General for Health and Food Safety, 11, rue E. Ruppert, L-2920, Luxembourg, Luxembourg
[b] Federal Institute for Risk Assessment (BfR), Berlin, Germany

ARTICLE INFO

Keywords:
SCCS
Scientific Opinion
Hydroxyapatite
Nano
Regulation 1223/2009
CAS 1306-06-5
EC 215-145-7

ABSTRACT

In response to the concerns of the European Commission about potential absorption and entry of nanoparticles of hydroxyapatite into the cells when used in oral cosmetic products, the Scientific Committee on Consumer Safety (SCCS) was requested to provide a safety assessment of hydroxyapatite (nano). After making a detailed evaluation of the data provided in the submissions and scientific literature, the SCCS considered needle-shaped hydroxyapatite (nano) to be of concern due to its potential toxic effects, and stated that it should not be used in cosmetic products. In terms of other shapes of hydroxyapatite (nano), the available evidence was insufficient to allow drawing a conclusion on the safety of hydroxyapatite (nano) when used in oral cosmetic products up to a concentration of 10%.

Hydroxyapatite (CAS 1306-06-5, EC 215-145-7), not regulated in Cosmetic Regulation (EC) No 1223/2009, is used as an abrasive, bulking and emulsion stabilising agent in cosmetic products. According to the applicant, in nano uncoated form, hydroxyapatite is used in leave-on and rinse-off oral cosmetic products such as toothpastes, tooth whiteners and mouth washes, with a maximum concentration of 10%. The total number of 35 notifications of cosmetic products containing hydroxyapatite (nano) has been received by the European Commission.

Many hydroxyapatite (nano) materials have been shown to be easily taken up into cells and to exert there a variety of adverse effects including cytotoxicity, induction of oxidative stress, apoptosis, and inflammatory responses. Because of potential absorption and entry of nanoparticles of hydroxyapatite into the cells, the European Commission has concerns about the use of the ingredient in nano form. In response to these concerns, the Scientific Committee on Consumer Safety (SCCS) was requested to provide a safety assessment of hydroxyapatite (nano) in the above-mentioned categories of products, taking into account the reasonably foreseeable exposure conditions. Moreover, the SCCS was requested to address any further scientific concerns with regard to the use of hydroxyapatite (nano) in cosmetic products.

The safety of hydroxyapatite (nano) in oral cosmetic products was assessed by the SCCS based on the data provided by the applicants that corresponded to the SCCS Guidance on the Safety Assessment of Nanomaterials in Cosmetics (SCCS 1484/12) and on the available knowledge from the scientific literature.

The data submitted by the applicants corresponding to the SCCS Guidance (SCCS 1484/12) was limited and not in line with the SCCS Memorandum on Relevance, Adequacy and Quality of Data in Safety Dossiers on Nanomaterials (SCCS/1524/13). According to both the data provided in the submissions and in the scientific literature, the test materials used in toxicological studies mostly lacked information on characterisation or were different from the materials used in the studies under evaluation. Almost none of the toxicological studies complied with relevant test guidelines in terms of study design.

No study, either from those provided in the submissions or available in the scientific literature, was identified that would have allowed the identification of a point of departure for risk assessment. However, there are studies published in the open literature suggesting that hydroxyapatite materials that were different from the materials under evaluation might be taken up locally and hydroxyapatite (nano) might exert systemic effects after oral administration. As no information on long-term exposure was available, it was not possible to draw any conclusion on whether repeated, long-term oral exposure to hydroxyapatite (nano) would cause adverse effects. Additional concerns with regard to the use of hydroxyapatite (nano) in cosmetic products were raised by the SCCS, in particular, over needle-shaped hydroxyapatite (nano) in relation to its potential toxicity, as indicated in the literature.

In summary, after making a detailed evaluation of the data provided in the submissions and scientific literature, the SCCS considered needle-shaped hydroxyapatite (nano) to be of concern due to its potential toxic

* Corresponding author.
[1] Rapporteur of the Opinion.

https://doi.org/10.1016/j.yrtph.2018.07.018
Received 19 July 2018; Accepted 22 July 2018
Available online 17 August 2018

effects, and stated that it should not be used in cosmetic products. However, in terms of other shapes of hydroxyapatite (nano), the available evidence was insufficient to allow drawing a conclusion on the safety of hydroxyapatite (nano) when used in oral cosmetic products up to a concentration of 10%. To produce a conclusive safety assessment of hydroxyapatite (nano), toxicological data specific for the materials included in the submissions for safety assessment would be needed, unless a close similarity with the materials used in the available studies can be demonstrated to allow data read-across.

Opinion to be cited as: SCCS (Scientific Committee on Consumer Safety), Opinion on hydroxyapatite (nano), 16 October 2015, SCCS/1566/15, revision of 16 March 2016.

Authors of the Opinion

SCCS members: Dr. U. Bernauer (rapporteur), Prof. Q. Chaudhry (chairperson), Prof. M. Dusinska, Dr. W. Lilienblum, Prof. T. Platzek, Dr. J. van Benthem

SCENIHR members; Prof. P. H. M. Hoet, Dr. K. Rydzynski

External experts: Prof. A. Bernard, Dr. O. Bussolati, Dr. N. von Götz, Dr. S. H. Doak, Dr. T. Jung.

SCCS Number: SCCS/1566/15.

Doi:/.

Adopted on: 16 October 2015, revision of 16 March 2016.

Link to the SCCS Opinion: https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_191.pdf.

Transparency document

Transparency document related to this article can be found online at https://doi.org/10.1016/j.yrtph.2018.07.018.