



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 “Fullerenes, Hydroxylated Fullerenes and hydrated forms of Hydroxylated Fullerenes”

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. In addition, the Commission Recommendation of 2011¹ on the definition of nanomaterial specifically addressed the issue of Fullerenes by stating: ‘*By derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials*’.

The nanomaterials definition covers materials in the nano-scale that are intentionally made and are insoluble/partially-soluble or biopersistent (e.g. 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, the Commission shall refer it to the Scientific Committee on Consumer Safety (SCCS) for a full risk assessment.

The Commission services received 19 notifications under Article 16 of the Cosmetics Regulation via the Cosmetic Product Notification Portal (CPNP) for cosmetic products containing Fullerenes, Hydroxylated Fullerenes (CAS/EC No.: 99685-96-8/628-630-7, 11538-22-7/-, 182024-42-6/-0), and hydrated forms of Hydroxylated Fullerenes (for example CAS / EC No.: 2803976-74-9/-)

According to the notifications submitted via the CPNP, Fullerenes, Hydroxylated Fullerenes and hydrated forms of Hydroxylated Fullerenes are used in cosmetic products with different concentration and specifications. These ingredients are reported in CosIng database with the function of ‘antimicrobial’ and ‘skin conditioning-miscellaneous’ and in the open literature as ‘antioxidants’ (scavenging ability against free radicals). Currently, Fullerenes, Hydroxylated Fullerenes and hydrated forms of Hydroxylated Fullerenes are not regulated under the Cosmetic Regulation (EC) No. 1223/2009.

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011H0696>

The Commission has concerns on the use of Fullerenes, Hydroxylated Fullerenes and hydrated forms of Hydroxylated Fullerenes 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 Fullerenes, Hydroxylated Fullerenes and hydrated forms of Hydroxylated Fullerenes reported in the notifications.

2. Terms of reference

- (1) *In view of the above, and taking into account the scientific data provided, does the SCCS consider Fullerenes, Hydroxylated Fullerenes and hydrated forms of Hydroxylated Fullerenes safe when used in cosmetic products according to the maximum concentrations and specifications as reported via CPNP, taking into account reasonably foreseeable exposure conditions?*
- (2) *Based on the currently available scientific literature and SCCS' expert judgement, the SCCS is requested to assess any further scientific concerns with regard to the use of Fullerenes, Hydroxylated Fullerenes and hydrated forms of Hydroxylated Fullerenes in cosmetic products and whether a potential risk to human health can be identified according to Article 16(6) Reg.1223/2009.*

3. Deadline: six months from reception

4. Supporting documents

List of notifications of cosmetic products containing Fullerenes, Hydroxylated Fullerenes and hydrated forms of Hydroxylated Fullerenes received through the Cosmetic Products Notification Portal (CPNP).

The SCCS adopted this mandate by written procedure on 6 July 2021.