SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion on Gold (nano) - Colloidal Gold (nano) [CAS No 7440-57-5 / EC No. 231-165-9], Gold Thioethy lamino Hyaluronic Acid (nano) [CAS No. 1360157-34-1/ EC No. not available] and Acetyl heptapeptide-9, Colloidal gold (nano) [CAS / EC No. not available]

Commission Department requesting the Opinion: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

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.

That definition covers only materials in the nano-scale that are intentionally made and are insoluble/partially soluble or biopersistent (e.g. some 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 under Article 16 of the Cosmetics Regulation via the Cosmetic Product Notification Portal (CPNP):

- 236 notifications for cosmetic products containing Gold (68 notifications) and Colloidal Gold (168 notifications) with CAS No 7440-57-5 and EC No. 231-165-9 in nano form, as reported in the attached list. Gold, without any reference to the nano form, is reported in CosIng database as a colorant (CI 77480) and it is regulated according to entry 133 of Annex IV (IV/133) of the Cosmetic Regulation (EC) No 1223/2009. Colloidal Gold without any reference to the nano form is reported in CosIng with antimicrobial and skin conditioning functions. According to the available notifications, both ingredients (Gold and Colloidal Gold) are used in nano form in leave-on/rinse off skin cosmetic products with different concentrations and specifications as reported in the attached list.

- 11 notifications for cosmetic products containing Gold Thioethylamino Hyaluronic Acid [CAS No. 1360157-34-1, EC No. not available] in nano form, as reported in the attached list. Gold Thioethylamino Hyaluronic Acid without any reference to the nano form is reported in the CosIng database with the function of “skin conditioning”. It is not regulated under the Cosmetic Regulation
(EC) No 1223/2009. According to the notifications submitted, this ingredient is used in dermal, leave-on skin care cosmetic products, with different concentrations and specifications as reported in the attached list.

- 18 notifications for cosmetic products containing Acetyl heptapeptide-9, Colloidal gold [CAS and EC No. not available] in nano form, as reported in the attached list. Acetyl heptapeptide-9, Colloidal gold (nano) is not reported in the CosIng database and it is not regulated under the Cosmetic Regulation (EC) No 1223/2009. According to the notifications submitted, this ingredient is used in dermal, leave-on and skin care cosmetic products, with different concentrations and specifications as reported in the attached list.

The Commission has concerns on the use of Gold - Colloidal Gold, Gold Thioethylamino Hyaluronic Acid and Acetyl heptapeptide-9, Colloidal gold in nano form 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 the nano form of Gold - Colloidal Gold, Gold Thioethylamino Hyaluronic Acid and Acetyl heptapeptide-9, Colloidal gold reported in the notifications listed in the annex to this mandate.

2. Terms of reference

(1) In view of the above, and taking into account the scientific data provided:

a) does the SCCS consider the nanomaterials Gold and Colloidal Gold safe when used in leave-on/rinse off skin cosmetic products according to the maximum concentrations and specifications reported in the attached list, taking into account reasonably foreseeable exposure conditions?

b) does the SCCS consider the nanomaterial Gold Thioethylamino Hyaluronic Acid safe when used in leave-on cosmetic products according to the maximum concentrations and specifications reported in the attached list, taking into account reasonably foreseeable exposure conditions?

c) does the SCCS consider the nanomaterial Acetyl heptapeptide-9, Colloidal gold safe when used in leave-on cosmetic products according to the maximum concentrations and specifications reported in the attached list, taking into account reasonably foreseeable exposure conditions?

(2) Does the SCCS have any further scientific concerns with regard to the use of

a) Gold - Colloidal Gold in nano form in cosmetic products?

b) Gold Thioethylamino Hyaluronic Acid in nano form in cosmetic products?

c) Acetyl heptapeptide-9 Colloidal gold in nano form in cosmetic products?

3. Deadline: six months from reception
4. Supporting documents

List of notifications of cosmetic products containing Gold - Colloidal Gold, Gold Thioethylamino Hyaluronic Acid and Acetyl heptapeptide-9, Colloidal gold in nano form received through the Cosmetic Products Notification Portal (CPNP).

The SCCS adopted this mandate at the SCCS plenary meeting on 30/31 October 2019.