

## SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

**Request for a scientific opinion:** Styrene/Acrylates copolymer (nano) CAS No 9010-92-8, EC No 927-710-1 and Sodium styrene/Acrylates copolymer (nano) CAS No 9010-92-8.

### 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 8 notifications of cosmetic products containing Styrene/Acrylates copolymer CAS No 9010-92-8, EC No 927-710-1 and Sodium styrene/Acrylates copolymer CAS No 9010-92-8 in nano forms, as reported in the attached list. These ingredients are reported in the CosIng database without any reference to the nano form with the function of film forming and opacifying, but they are not regulated under Cosmetic Regulation (EC) No 1223/2009. According to the applicants, the ingredients are used in nano coated form in leave-on cosmetic products with maximum reported concentration limit of 0.06% and specifications as reported in the attached list.

The Commission has concerns over safety of the use of Sodium styrene/Acrylates copolymer (nano) and Styrene/ acrylates copolymer (nano) in cosmetic products.

The Commission performed a 12 weeks call for data with deadline of June 2015 where interested parties were invited to submit any relevant scientific information on the safety of Styrene/Acrylates copolymer (nano) (CAS No 9010-92-8, EC No 927-710-1) and Sodium styrene/Acrylates copolymer (nano) (CAS No 9010-92-8) used in cosmetic products and in particular data regarding all toxicological end-points and an indication on the suggested concentration safe limits for these ingredients. The documentation received by Commission is in the annex to this mandate.

Therefore, the Commission is requesting the SCCS a safety assessment of the nano form of Styrene/ acrylates copolymer and Sodium styrene/Acrylates copolymer 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 Styrene/ acrylates copolymer and Sodium styrene/Acrylates copolymer when used in leave-on cosmetics products with a maximum concentration limit of 0.06%, taking into account the reasonably foreseeable exposure conditions.*
- 2. SCCS is requested to address any further scientific concerns with regard to the use of Styrene/ acrylates copolymer and Sodium styrene/Acrylates copolymer in nano form in cosmetic products.*

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

## **4. Supporting documents**

- List of notifications of cosmetic products containing Styrene/ acrylates copolymer and Sodium styrene/Acrylates copolymer in nano forms received through the Cosmetic Products Notification Portal.
- Call for Data on Styrene/Acrylates copolymer (nano) and Sodium styrene/Acrylates copolymer (nano). European Commission DG GROW. 2015
- CIR "Final Report on the Safety Assessment of Acrylates Copolymer..." of 2002 to the EU Commission.
- Position paper of the EPDLA