



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Ecosystems I: Chemicals, Food, Retail

F2. Bioeconomy, Chemicals & Cosmetics

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion on the safety of aluminium in cosmetic products - Submission IV

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

1. Background

Aluminium (Al) and Al compounds are used in a variety of cosmetic products, predominantly in deodorants, antiperspirants, lipsticks, and toothpastes. Several Al compounds are regulated in different entries of the Cosmetics Regulation (EC) No 1223/2009¹.

In 2013, a risk assessment issued by the Norwegian Scientific Committee for Food Safety reported that cosmetic products, and in particular antiperspirants, constitute a significantly larger contribution to the total systemic Al exposure compared to diet at least for the Norwegian population that was used in the study. As a result, SCCS was mandated to evaluate the possible risk for human health arising from the presence of Al in cosmetics. The assessment was based on products and aluminium compounds that contributed to the highest consumer's exposure, namely antiperspirants/deodorants, toothpastes, and lipsticks.

In its Opinion SCCS/1525/14², the SCCS concluded that, due to the lack of adequate data on dermal penetration, the requested risk assessment could not be performed³. In 2016, industry submitted a new safety dossier to address the dermal penetration and the fate of Aluminium (after skin application) based on a human exposure study. At its plenary meeting on 3-4 March 2020, the SCCS adopted its final Opinion SCCS/1613/19⁴ and in March 2021 and addendum⁵ to this Opinion was published.

¹ Annex III (entry 50 - Aluminium Zirconium Chloride Hydroxide, and entries 189, 190, 192 - hair dyes), in Annex IV (entries 117, 118, 119, 150 - colorants) and Annex VI (entry 27a – coating for UV-filter).

² SCCS (Scientific Committee on Consumer Safety), Opinion on the safety of aluminium in cosmetic products, 27 March 2014, SCCS 1525/14, revision of 18 June 2014.

³ “Aluminium is a known systemic toxicant at high doses. The SCCS is of the opinion that due to the lack of adequate data on dermal penetration to estimate the internal dose of aluminium following cosmetic uses, risk assessment cannot be performed. Therefore, internal exposure to aluminium after skin application should be determined using a human exposure study under use conditions” (Opinion SCCS/1525/14).

⁴ SCCS (Scientific Committee on Consumer Safety), Opinion on the safety of aluminium in cosmetic products, preliminary version of 30-31 October 2019, final version of 03-04 March 2020, SCCS/1613/19.

⁵ SCCS (Scientific Committee on Consumer Safety), Addendum to the scientific opinion SCCS/1613/19 on the safety of aluminium in cosmetic products - Submission II, preliminary version of 15 December 2020, final version of 30-31 March 2021, SCCS/1626/20.

In the addendum, the SCCS concluded that the use of aluminium compounds is safe at the equivalent aluminium concentrations up to (a) 6,25 % in non-spray deodorants or non-spray antiperspirants, (b) 10,60 % in spray deodorants or spray antiperspirants, (c) 2,65 % in toothpaste, and (d) 14 % in lipstick

Following the discussion at the Cosmetics Working Group held on 25 June 2020 and in light of the comments received on the use of Aluminium compounds in a variety of products other than deodorants, antiperspirants, lipsticks and toothpastes, the Commission considered opportune to request from industry to submit additional information on the ‘other product categories’ and on the aggregate exposure not only from cosmetics.

In March 2021, industry submitted a dossier focusing on the aggregate exposure to aluminium concerning the European population when considering the use of cosmetics and personal care products, medicines (e.g., antacids) and dietary intake and the SCCS was requested to perform a safety assessment in view of the new information provided.

In its Opinion SCCS/1644/22⁶, the SCCS concluded that Aluminium compounds are safe when used in non-sprayable product categories at the maximum levels indicated in Tables 4 and 6 of the SCCS Opinion; and in sprayable products, at the maximum levels indicated in Table 4 of the SCCS Opinion, provided that the percentage of particles/droplets with a diameter of less than 10 µm does not exceed 20 % of the total aerosolised particles/droplets. In addition, the SCCS noted that based on a realistic aggregate exposure scenario used in that submission, contribution to Aluminium exposure from food may be at a similar order of magnitude to that from cosmetics. This information taken together with the conservative nature of the exposure estimates for cosmetics that were used for calculating the MOS, SCCS concluded that the aggregate exposure to aluminium from cosmetic and non-cosmetic sources may exceed safe limits for consumers at the highest exposure ranges.

The current request concerns the update of use concentrations based on submission IV by the Aluminium consortium, which comprises an amendment to the probabilistic exposure assessment report. The Commission, therefore, requests the SCCS to evaluate the information submitted and review its conclusions in SCCS/1613/19, SCCS/1626/20, and SCCS/1644/22, accordingly.

2. Terms of reference

- (1) In light of the new data provided, does the SCCS consider Aluminium compounds safe when used in cosmetic products? In the event that the estimated exposure to Aluminium from cosmetic products is found to be of concern, SCCS is asked to recommend safe concentration limits for each category and product type.*
- (2) Does the SCCS have any further scientific concerns regarding the use of relevant Aluminium compounds in cosmetic products taking into account the newly submitted information?*

3. Deadline: 6 months

⁶ SCCS (Scientific Committee on Consumer Safety), Opinion on the safety of aluminium in cosmetic products - Submission III, preliminary version of 6 May 2022, final version of 1 February 2023, Corrigendum 21 March 2023, SCCS/1644/22.

4. Supporting documents:

Aluminium - CE consortium updated use concentrations - 28-04-23

Creme Global - Evaluating Aggregate Exposure to Aluminium from Food, Cosmetics and Personal Care Products and Antacids (Addendum), dated 22nd September 2022

Comments by the Cosmetics Europe Aluminium consortium under the public consultation for the preliminary opinion on the safety of Aluminium (SCCS/1644/22). Final 25/07/22

The Powder Company AG -input on Aluminium in Talc.

The SCCS approved this mandate during plenary meeting on 6-7 June 2023. The last supporting document has been accepted on 3 October 2023.