Scientific Committee on Consumer Safety

SCCS

OPINION

on the safety of aluminium in cosmetic products

- Submission IV -

The SCCS adopted this document
during the plenary meeting on 27 March 2024

ACKNOWLEDGMENTS

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This Opinion has been subject to a commenting period of eight weeks after its initial publication (from 15 December to 16 February 2024). Comments received during this period were considered by the SCCS. For this Opinion, main changes occurred in the following sections: SCCS comment under section 3.1, the section 3.2.1, SCCS comments under section 3.2.4.1, 3.2.4.4, 3.2.4.5, and 3.4, as well as related sections in discussion and conclusions.

All Declarations of Working Group members are available on the following webpage:
Register of Commission expert groups and other similar entities (europa.eu)

1. ABSTRACT

The SCCS concludes the following:

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.*

The SCCS considers that aluminium compounds are safe when used:

- in non-sprayable product categories at the maximum levels indicated in Tables 1 and 2.

- in sprayable products, at the maximum levels for the total formulation (*i.e.* including propellant) indicated in Table 1, 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. Since the Applicant's data submission indicated that aluminium is not used in sunscreen aerosol sprays, this Opinion does not cover sunscreen aerosol sprays.

- the SCCS considers that aluminium in talc is not bioavailable. Therefore, talc with aluminium-content of up to 2% may be used in cosmetic products.

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?*

As mentioned in Opinion SCCS/1644/22, aluminium does not belong to substances classified as CMR 1A or 1B, so that only exposure from cosmetic uses was considered in this safety assessment with the exposure assessment based on maximum use levels for cosmetic ingredients. However, as evaluated in SCCS/1644/22, aggregated exposure from cosmetics and food may exceed safe limits for consumers at the highest exposure ranges.

It needs to be noted that this Opinion specifically covers the risk to consumers from exposure to aluminium from cosmetic products. As such, this Opinion does not address the safety of the use of talc in cosmetic products beyond the safety of the aluminium content in talc.

This Opinion does not apply to nano forms of aluminium for which a separate specific safety assessment would be needed.

Keywords: SCCS, revision, scientific opinion, aluminium, submission IV, Regulation 1223/2009

Opinion to be cited as: SCCS (Scientific Committee on Consumer Safety), Opinion on the safety of aluminium in cosmetic products - Submission IV, preliminary version of 14 December 2023, final version of 27 March 2024, SCCS/1662/23

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SCCS

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2. MANDATE FROM THE EUROPEAN COMMISSION

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 1223/2009[1].

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/1525/14[2], the SCCS concluded that, due to the lack of adequate data on dermal penetration, the requested risk assessment could not be performed[3]. 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/1613/19[4] and in March 2021 and addendum[5] to this Opinion was published.

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/1644/22[6], 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,

[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.
[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.

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.

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. OPINION

This new Opinion includes updated use concentrations based on information from Applicant 1. It also includes information submitted by Applicant 2 specifically on the mineral talc, which is used in body/baby/foot powders. No updates have been made regarding toxicology.
It needs to be noted that this Opinion specifically covers the risk to consumers from exposure to aluminium from cosmetic products. As such, this Opinion does not address the safety of the use of talc in cosmetic products beyond the safety of the aluminium content in talc.

3.1 CHEMICAL AND PHYSICAL SPECIFICATIONS

Physicochemical properties of aluminium compounds that can generally be used as cosmetic ingredients have been summarised in Annex I of the SCCS Opinion SCCS/1613/19. These encompass aluminium compounds in water-soluble and water-insoluble form. The water-soluble Al-containing compounds are simple inorganic salts, simple organic salts, aluminium benzoate, and chlorohydrates, which can be used in skin care products. Water-insoluble aluminium containing compounds can be minerals, glasses and clays, aluminium lakes, carbohydrates, fatty acid salts, which are typically added to cosmetic products as bulking agents, coloured pigments, and sometimes as mild abrasives.

An industry survey that indicates the substances actually in use along with their aluminium content has been evaluated in SCCS/1644/22. The INCI names and CAS numbers of the respective substances are given in Tables 2 and 3 of that Opinion. The respective physicochemical properties of the substances can be retrieved from Annex 1 of SCCS/1613/19.

Additional information on aluminium-containing talc has been provided in a new dossier by Applicant 2. This Applicant states that the natural Al-value of the talc usually exceeds the value included in SCCS/1644/22 (Table 6). Thus, Applicant 2 requests to change the respective maximum aluminium content of talc to 2%.

Applicant 2 further presents considerations on the release of aluminium from talc: According to this Applicant, the occurring aluminium is firmly bound in a silicate structure in the form of chlorite minerals. The stability of this structure makes the present Al insoluble and inaccessible for most biological organisms, but also hard to remove. Separating the chlorite would require aggressive chemical conditions that would pose a much higher risk to the talc product than the inert chlorite mineral.

According to Applicant 2, as explained in works done by Blount and Vassiliou, 1983, the term "talc" often may lead to confusion since it is both used for the rock as well as the mineral. Natural talc ore generally consist of the mineral talc ($Mg_3Si_4O_{10}(OH)_2$) as well as associated minerals, mainly carbonates such as dolomite ($MgCa(CO_3)_2$) and magnesite ($MgCO_3$) as well as different chlorite minerals. Since talc is a secondary mineral resulting from metamorphosis of other silicate minerals (Klockmann et al., 1980), chlorites are present in nearly every talc deposit. A general formula for chlorites can be stated as $[Mg, Al, Fe]_6[(Si,Al)_4O_{10}](OH)_8$. The most common types of chlorite in talc are clinochlore, penninite and sheridanite.
The descriptions of Blount and Vassiliou, 1983, fit very well with XRD analysis (Cu K-α, λ=1,54 A, 40 kV, 15 mA) done with samples of euroMinerals starting material and finished goods.

According to Applicant 2, while aluminium salts commonly used in cosmetics, *e.g.* aluminium chlorohydrate in deodorants, easily dissolve in water (Flarend et al., 2001), this is not the case for most alumosilicates such as chlorites. Alumosilicates generally exhibit very slow

reaction kinetics and can be considered insoluble if not put under rough chemical and thermal conditions (Priest, 2004; Smith et al., 2013; Smith and Carroll, 2016).
Despite leading to frequent misunderstandings, the presence of chlorite minerals in talc for pharmaceutical and cosmetic applications is well known. Most pharmacopoeias (Ph.Eur., USP, JP) have aluminium limits of ≤ 2% and iron limits of ≤ 0.25 in their respective talc monographs. The main sources of both elements in talc are typically chlorite minerals.

Elemental analysis carried out for quality control of the talc product in talc Pharma TPC is routinely done using microwave-assisted acid digestion and inductively coupled mass spectroscopy (ICP-MS). For sample preparation, 0.2 g of talc sample material are mixed with 1 mL pure water, 5 mL of concentrated nitric acid (69 % HNO3) and 1 mL of concentrated hydrochloric acid (HCl, 30 %). The suspension is heated to 200 °C with a hold time of 30 minutes. Under these extreme conditions, Al is dissolved yielding typical results of 0.3-0.5 %.

For comparison, two samples of batch no. 140723 were prepared adding only 10 mL of 0.1% HCl instead of the usual mixture and heating to 40°C for 2 hours. Elemental analysis was then carried out using the same ICP-MS method. This experiment resulted in only 36 ppm and 35 ppm of Al respectively dissolved from the two samples analysed. These results fit well with the insolubility of Al stated for such silicate compounds in literature (Priest, 2004; Smith et al., 2013; Smith and Carroll, 2016).

In the light of these results, it can be noticed that even much higher Al contents in talc resulting from the accompanying chlorite minerals are practically insoluble and therefore are not bioavailable at all. Additionally, these Al contents cannot simply be lowered without destroying the mineral in its functionality, in its physicochemical properties. Consequently, a body/baby/foot powder that contains 100 % talc can be assessed as safe, fully in line with the present CIR document regarding talc in cosmetics, taking into account the specification reported and laid down there (USP talc: Al ≤ 2 %) (Cosmetics Ingredient Review (CIR), 2013).

SCCS comment
From the received information and further literature search, it can be concluded that aluminium is not released and therefore not bioavailable from talc. In conclusion, body/baby/foot powders containing talc do not need to be considered in the aggregate exposure assessment for aluminium from cosmetics, and the SCCS agrees that a maximum of 2% aluminium in talc can be considered safe with regard to any risks from aluminium.

3.2 EXPOSURE ASSESSMENT & TOXICOKINETICS

3.2.1 Function and uses

Functions and uses are listed in Opinion SCCS/1644/22 based on a company survey from 2016 that included seven large multi-national companies from the Al-consortium, which together represent around 40% of the EU market share. The data for Aluminium in toothpaste is based on a survey in one company in 2020.
Main uses include antiperspirants, toothpaste, lipstick and other make-up products and face creams, but Al is used also in other product categories.

In a new submission, Applicant 2 has declared that talc is used in body powders, including foot and baby powder.

According to information provided by Applicant 1 during public consultation no other Al-containing compounds than talc had been reported in the survey for use in body/baby/foot powders. Furthermore, according to Applicant 1 it can be stated, that in general powder products are formulated to contain insoluble ingredients, such as kaolin, mica, perlite or Aluminium stearates/myristates, apart from talc (Steiling *et al.,* 2018). Such insoluble substances will not lead to the release of Aluminium upon inhalation and dermal exposure, in analogy to what the SCCS has concluded for talc. As far as dermal exposure is concerned, body powders can conservatively be covered by the "body lotion" exposure, although body powders are usually not applied to the whole-body skin surface, but on selected areas only. Also, the applied amount is certainly less for body powders compared to that of body lotion.

According to Applicant 1, for inhalation exposure assessment, it is important to differentiate between compact (pressed) powders and loose powders. Compact powders contain significantly higher amounts of binders compared to lose powders, in addition to being compressed in cake form. As a result, the generation of airborne particles during use is minimized, which makes potential exposure by inhalation highly unlikely (Steiling et al., 2018). Loose powders may lead to inhalation exposure during application, the extent depending on the particle size distribution, the dustiness of the product, and how close to the breathing zone the product is applied. However, due to insolubility in the respiratory tract and thus, absence of bioavailability, systemic exposure to Aluminium is negligible, similarly to what the SCCS concluded for talc.

With regards to Antiperspirants/Deodorants Applicant 1 would like to clarify that the existing risk assessment, presented in the July 2022 submission covers use of hand and foot sweat control products, including powders.

According to Applicant 1, tooth powder is an alternative to toothpaste. Tooth powder is intended for brushing as with traditional toothpaste and spit out. Tooth powder is applied to a wet toothbrush and then directly placed in the mouth for oral use. Due to the adhesion to the wet toothbrush, use parameters, and large particle size of the powder, the risk of inhalation exposure to consumers is minimal to absent.

Taken together, according to Applicant 1 no additional systemic exposure to Aluminium needs to be considered from powder products in the existing aggregate exposure assessment.

SCCS comment

The SCCS considers that for aluminium-containing compounds other than talc, the same level of evidence for the lack of release of aluminium from powder products has not been provided. In the absence of such evidence, the SCCS notes that aluminium-release data are needed to determine inhalation exposure to aluminium from body/ baby/foot powders.

3.2.2 Dermal / percutaneous absorption

The data related to dermal/percutaneous absorption were assessed and commented upon by the SCCS in SCCS/1613/19. Below is a brief summary.

Dermal absorption was calculated from an exposure study with 6 female volunteers after application of 0.75 g antiperspirant per axilla on 100 cm^2, respectively. The antiperspirant contained Aluminum-Chlorhydrate which had been doped with radioactive ^{26}Al and the volunteers were biomonitored for ^{26}Al in 24h-urine (TNO, 2019). This yielded a skin absorption value of 0.00052%. Combined with the Al found in the feces in the same study (0.0014%), this yields an overall percentage of bioavailable Al of 0.00192%.

SCCS comment
A dermal absorption percentage of 0.00192% was used in the presented exposure calculation. This is considered a valid absorption value, which was derived from a study with an antiperspirant. Due to occlusion and the formulation characteristics of antiperspirants, the dermal absorption for antiperspirants is considered to be a conservative value that is also valid for the other cosmetic products addressed in this Opinion.

3.2.3 Other studies on toxicokinetics

Toxicokinetic studies were reviewed in SCCS/1613/19, and were summarised as follows:

Oral absorption: EFSA (2008) concluded that a value of 0.3% oral bioavailability was appropriate to use in human risk assessment for soluble aluminium in drinking water (*i.e.* without food) and 0.1% with food.

Lung absorption: Taken together, all available data suggest that absorption of aluminium from lung deposits in the blood is low. For the purposes of lung exposure modelling and risk assessment, a conservative value for aluminium uptake by the lung is 3% (Jones & Bennett, 1986; DeVoto & Yokel, 1994).

SCCS comment
The SCCS considers that oral bioavailability of 0.1% is an appropriate value for use in risk assessment for indirect ingestion after removal from the upper respiratory tract by the mucociliary elevator.

Regarding inhalation, as reported in the SCCS/1613/19, a conservative value for aluminium uptake by the lung of 3% is an appropriate value for use in risk assessment. From the upper respiratory tract, no data on bioavailability is available, but since mucociliary clearance will lead to expectorate or swallowing of the Al trapped in that part of the body, intestinal resorption values of 0.1 or 0.3% can be used (EFSA, 2008).

3.2.4 Calculation of SED/LED

In the most recent SCCS Opinion SCCS/1644/22, a comprehensive report on single product and aggregate exposure to Al via cosmetics, as well as an aggregate assessment of Al in cosmetics, medicines (antacids) and food has been evaluated. The assessment is based on an occurrence survey among the European industry and included a probabilistic aggregate exposure assessment, and additional deterministic calculations for product categories not included in the model used for the probabilistic assessment. During the public consultation, Applicant 1 submitted an amendment to the probabilistic exposure assessment report with updated use concentrations, which were not taken into account for the final Opinion, but are evaluated in this updated Opinion.

Furthermore, new information on Aluminium concentrations in talc have been submitted by Applicant 2.

3.2.4.1 Concentrations in cosmetics

According to Applicant 1, the use concentrations in the probabilistic assessment (Scenario 1b) were updated for the following reasons:

a) The use survey on which the exposure assessments were based dates back to 2016. Usage in the market has changed and therefore the concentrations underlying the assessment needed adjustment. While the updates seem not very significant and show that use concentrations are relatively stable over time and therefore have probably little impact on the market, the consortium sees it as important to have the final Opinion and the resulting regulatory entry based on the most recent use concentrations.

b) The consortium noticed that it is possible to merge some product types from the list of products not included in the probabilistic model with the product types that are, thereby reducing the overall list pf product types. This necessitated further adjustments of the use concentrations.

According to Applicant 1, Scenario 1b is similar to Scenario 1 as it assumes 100% of cosmetic products contain Aluminium and concentrations are represented as single maximum values for each product. For a few products, the concentrations used in Scenario 1b are higher than the concentrations used in Scenario 1 and so it provides a more conservative estimate of exposure. The concentrations for Scenario 1b are shown in Table 1 (Table 4A in SCCS/1644/22).

Table 1: Concentrations of aluminium in each product type and category for Scenario 1b.

	Product as labelled in the model	Aluminium concentrations (%) in products in Scenario 1b
1	AfterShave	2.15%
2	BarSoap	4%
3	BodyLotion	3.81%
4	BodySpray	1.18%
5	DeoRollOn – Gel	6.18%
6	DeoRollOn – RollOn	5.63%
7	DeoRollOn – Stick	7.73%
8	DeoRollOn – Wipes	0%
9	DeoSpray – Anti-Perspirant	3.24%
10	DeoSpray – Pump	4.88%
11	EaudeParfum, EaudeToilette	0.05%
12	EyeShadow	43.31%
13	EyeLiner	15.76%
14	FaceMoisturizer	10.59%
15	HairSpray	0.15%
16	HairStyling	6.7%
17	HandCream	0.86%
18	Lipstick	14.62%
19	LiquidHandSoap	0.89%
20	LiquMakeupFoundation	23%
21	MakeupRemover	10.59%
22	Mascara	3.13%
23	Mouthwash	0%
24	RinseoffConditioner	7.14%
25	Shampoo	7.14%
26	Showergel	0.89%
27	Toothpaste	3.18%

In addition, Applicant 1 submitted deterministic assessments for product types not included in the probabilistic assessment. According to Applicant 1, they include product categories which are only used periodically such as seasonal beach products (sun cream/lotion), as well as other products with infrequent use or very low exposure such as hair colour and perms,

decolouration and oxidative colouration products, or products for sweat control on feet and hands (other products with and without AP[7]).

Because these product types were not part of the probabilistic model, Applicant 1 proposed to work these exposures into the overall assessment in a deterministic way. The respective proposed calculations were submitted as part of Applicant 1's response to the public consultation.

Table 2: Concentrations of aluminium in product categories not included in the probabilistic assessment (Applicant 1).

Product type	Number of unique formulas	Maximum concentration of Al in products (%)	Quantity of products sold (tons) with aluminium	Occurrence
Other products with and without AP	6	2.8%	143.6	69.29%
Shaving products	1	0.094%	0.57	0.00%
Nail varnish	562	3.618%	190.09	31.00%
Eye contour products	53	1.290%	99.33	41.01%
Sun cream/lotion	163	1.3%	3396.81	29.05%
Hair Colour and Perms	60	0.002%	987.11	3.26%
Lip care products: Lip balm	20	0.606%	124.44	25.20%
Other products – Decolouration	21	5.01%	850.52	9.71%
Other products – oxidative colouration	272	0.120%	1661.23	6.95%

Applicant 2 requests an update of the use concentrations regarding talc, claiming that the data provided by Applicant 1 on talc as included in SCCS/1644/22 is not representative for the talc industry. According to Applicant 2, talc can be used in baby powders up to a content of 100%, and talc may contain up to 2% Al (submitted analytical values show percentages of 0.3-0.5% w/w).

SCCS comment
According to information from Applicant 1, the concentrations for sprays in Table 1 relate to the total formulation of the spray (*i.e.* including propellant). In the calculations of inhalation exposure for sprayable products, the assumption is made that the percentage of particles/droplets with a diameter of less than 10 µm does not exceed 20% of the total aerosolised particles/droplets. Since the respective data were not made available to the SCCS, this pre-requisite needs to be captured in the conclusion.

The SCCS follows the argumentation of Applicant 2 that aluminium in talc can be considered as not bioavailable. Therefore, the SCCS agrees that the aluminium concentrations in talc

[7] AP: antiperspirant

used in cosmetics may be up to 2%. Consequently, the entry for talc from Applicant 1 was deleted in Table 2 above and replaced by the conclusions based on the data shared by Applicant 2.

3.2.4.2 Frequency of use and co-use

The frequencies of use and co-use included in the probabilistic aggregate exposure assessment have been discussed in SCCS/1644/22.

3.2.4.3 Amount per use

The amounts per use included in the probabilistic aggregate exposure assessment have been discussed in SCCS/1644/22. For the deterministic assessments, the parameters are given in chapter 3.2.4.5, Tables 5-9 and text.

3.2.4.4 Retention and bioavailability factors

The retention factors and bioavailability factors used in the probabilistic aggregate exposure assessment have been discussed in SCCS/1644/22. They are summarised in Table 3 below.

Table 3: Summary of assessment factors used in the probabilistic aggregate exposure assessment Scenario 1b (Table 10A in SCCS/1644/22)

Product	Dermal retention factor	Dermal penetration factor	Inhalation factor	Lung Bioavailability Factor (RF[a])	Upper airways factor (NRF[b])	Ingestion factor	Oral bioavailability factor
Food and beverages						100%	0.1%
Water						100%	0.3%
Antacids						100%	0.1%
AfterShave	100%	0.00192%					
BarSoap	1%	0.00192%					
BodyLotion	100%	0.00192%					
BodySpray	100%	0.00192%					
DeoRollOn – Stick	100%	0.00192%					
DeoRollOn – RollOn	100%	0.00192%					
DeoRollOn – Gel	100%	0.00192%					
DeoRollOn – Wipes	100%	0.00192%					
DeoSpray – Anti-Perspirant	23.5%	0.00192%	**1.208%**	3% (20%)	0.1% (80%)		
DeoSpray – Pump	23.5%	0.00192%	**1.208%**	3% (2%)	0.1% (98%)		
EaudeParfum EaudeToilette	80%	0.00192%	**1.213%**	3% (2%)	0.1% (98%)		
EyeShadow	100%	0.00192%					
Face Moisturizer	100%	0.00192%					
HairSpray	10%	0.00192%	**1.204%**	3% (20%)	0.1% (80%)		
HairStyling	10%	0.00192%					
HandCream	100%	0.00192%					
Lipstick	0%	0.00192%				100%	0.1%
LiquidHandSoap	1%	0.00192%					
LiquMakeupFoundation	100%	0.00192%					
Mascara	100%	0.00192%					
Mouthwash	10%	0.00192%				10%	0.1%
RinseoffConditioner	1%	0.00192%					
Shampoo	1%	0.00192%					
Showergel	1%	0.00192%					
Toothpaste	5%	0.00192%				5%	0.1%
EyeLiner	100%	0.00192%					
MakeupRemover	1%	0.00192%					

[a] Respirable Fraction

[b] Non-Respirable Fraction

SCCS comment

Compared to SCCS/1644/22, concentration values in products have been updated in the new probabilistic aggregate exposure assessment: Applicant 1 has now used higher concentrations for the product categories Bar Soap, Hair Styling, Liquid Hand Soap and LiquMakeup Foundation in the new Scenario 1b as well as more conservative inhalation parameters.

3.2.4.5 Exposure calculations and Scenarios for cosmetics

Probabilistic aggregate exposure calculations result in exposure estimates highlighted in Table 4.

Table 4: Summary statistics of the exposure to Al from the use of cosmetics per route of exposure for the four different scenarios provided by Applicant 1

Route	Statistic	Exposed Population				Total Population			
		Scenario 1	Scenario 1b	Scenario 2	Scenario 3	Scenario 1	Scenario 1b	Scenario 2	Scenario 3
Dermal	Count	104780	**104780**	104780	101364	104836	**104836**	104836	104836
	Mean*	0.01657	**0.01858**	0.002565	0.001727	0.01656	**0.01857**	0.002562	0.001663
	P50*	0.01004	**0.01102**	0.001087	0.0004282	0.01003	**0.011**	0.001085	0.0003614
	P95*	0.0529	**0.05988**	0.0102	0.007553	0.05283	**0.05987**	0.01019	0.007370
Ingestion	Count	95760	**95760**	95760	61064	104836	**104836**	104836	104836
	Mean*	0.03174	**0.03179**	0.0006820	0.0006595	0.02861	**0.02866**	0.0006146	0.0003831
	P50*	0.02617	**0.02611**	0.0002215	0.0001798	0.02342	**0.02342**	0.0001711	2.65e-05
	P95*	0.07635	**0.07683**	0.002450	0.002386	0.07404	**0.07471**	0.002314	0.001617
Inhalation Non-Respirable	Count	73328	**73328**	73328	48984	104836	**104836**	104836	104836
	Mean*	0.002787	**0.003756**	0.000932	0.001324	0.00192	**0.00259**	0.0006423	0.0005856
	P50*	5.4e-06	**1.712e-04**	3.80e-06	0.0002713	2.3e-06	**1.58e-05**	1.1e-06	0.0
	P95*	0.013054	**0.01761**	0.004840	0.005737	0.01089	**0.01473**	0.003906	0.003656
Inhalation Respirable	Count	73328	**73328**	73328	48984	104836	**104836**	104836	104836
	Mean*	0.019	**0.02592**	0.006355	0.008920	0.013084	**0.01786**	0.004383	0.003944
	P50*	3.4e-06	**7.25e-04**	6.14e-06	0.0007796	1.43e-06	**9.74e-06**	8.0e-07	0.0
	P95*	0.09735	**0.13124**	0.03445	0.04123	0.0804	**0.10971**	0.02746	0.02528
Total Systemic (Combined Oral, Dermal & Inhalation)	Count	104780	**104780**	104780	101413	104836	**104836**	104836	104836
	Mean*	0.06024	**0.0677**	0.00821	0.006820	0.06018	**0.06767**	0.008200	0.006577
	P50*	0.04486	**0.04785**	0.002665	0.001384	0.0448	**0.04781**	0.002659	0.001219
	P95*	0.1671	**0.19911**	0.03647	0.03317	0.1671	**0.19906**	0.03647	0.03238

* Units for Mean, P50 and P95 are µg/kg bw/day.

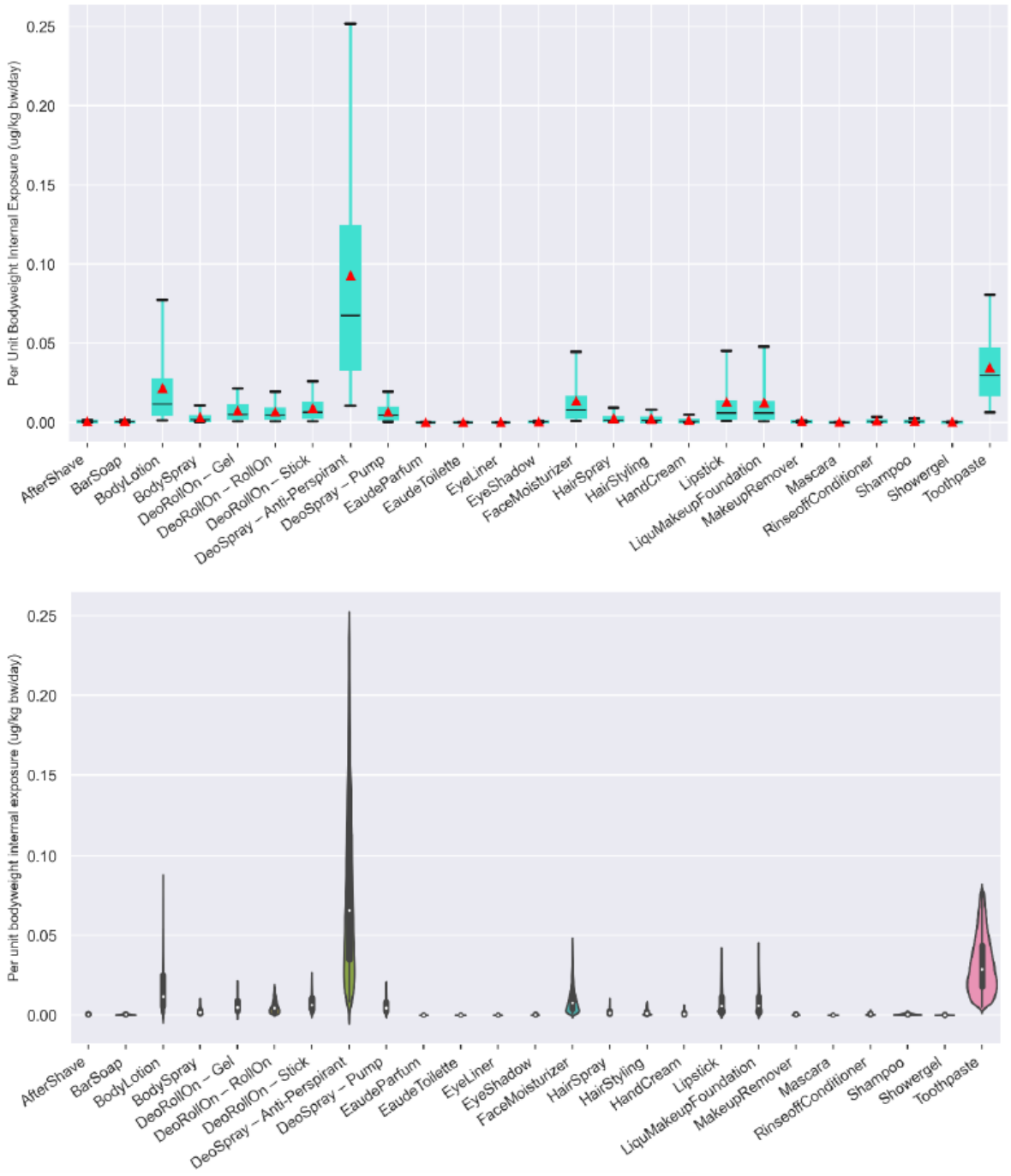

Figure 1: Distribution of internal exposure levels per cosmetic product, scenario 1b

Some products were not included in the aggregate assessment. Therefore, Applicant 1 has provided the following deterministic calculations for single products:

Other products with and without AP (antiperspirant)
These products are meant for sweat control on feet and hands.
Based on the comparable skin surface area, the daily exposure level of hand cream was taken as basis for the estimated daily exposure to these products.

Table 5: Deterministic assessment for products with and without AP

Product type	Max Al%	Daily exposure (mg/kg bw)	Total dermal exposure (mg/kg bw)	Calculated SED (µg/kg bw)	MOS
Hand cream	2.8	32.7	0.92	0.018	10,000

Shaving products

Shaving products are rinse-off products. Based on the comparable skin surface area, the daily exposure level of make-up remover was taken as basis for the estimated daily exposure to these products. In its preliminary Opinion, the SCCS considered that the exposure from these products was negligible, which is demonstrated here.

Table 6: Deterministic assessment for shaving products

Product type	Max Al%	Daily exposure (mg/kg bw)	Total dermal exposure (mg/kg bw)	Calculated SED (µg/kg bw)	MOS
Make-up remover	0.094	8.33	0.0078	0.00015	1,200,000

Nail varnish

In nail varnish, aluminium is present as colorant-lake, aluminium powder, mica, calcium aluminium borosilicate, and calcium sodium aluminium silicate.

After application of the liquid varnish, the drying process starts immediately and is completed within minutes, leaving on the nail a hard dry film. Moreover, due to its anatomical structure and chemical composition, the human nail plate acts as an excellent barrier for topically applied chemical substances (Walters et al. Int. J. Pharmaceutics 435, 10-21, 2012). Thus, there is no evidence that aluminium may penetrate in relevant amounts through the nail after the application of nail varnish.

Even in the unlikely event that a very minor residual amount will accidentally come into contact with the surrounding skin, the risk of possible penetration and thus, of systemic bioavailability, can be considered as negligible.

Eye contour products

Based on the comparable skin surface area, the daily exposure level of eye shadow was taken as basis for the estimated daily exposure to these products. It should also be noted that multiple products are unlikely to be applied on the same area (i.e., unlikely to apply a face care product to an area where eye contour products are applied). In its preliminary Opinion, the SCCS considered that the exposure from these products was negligible, which is demonstrated here.

Table 7: Deterministic assessment for products eye contour products

Product type	Max Al%	Daily exposure (mg/kg bw)	Total dermal exposure (mg/kg bw)	Calculated SED (µg/kg bw)	MOS
Eye shadow	1.29	0.33	0.004	0.00008	2,250,000

Sun cream/lotion
For the estimated daily exposure to these products, 18 g per person are assumed according to the SCCS NoG (2021). The safety assessment is very conservative because the exposure to beach products is seasonal rather than daily.

Table 8: Deterministic assessment for sunscreens

Product type	Max Al%	Daily exposure (mg/kg bw)	Total dermal exposure (mg/kg bw)	Calculated SED (µg/kg bw)	MOS
Sun cream / lotion	1.3	300	3.9	0.075	2,400

Hair colour and perms, oxidative and non-oxidative colouration, decolouration
This is a conservative safety assessment because the assumption is daily exposure, whereas the semi-permanent hair dyes are indicated to be applied once a week and the oxidative colouration is applied once a month only (SCCS NoG 2021).

Table 9: Deterministic assessment for hair colour and perms

Product type	Max Al%	Exposure per application	Total dermal exposure (partition factor 0.1)	Calculated SED (µg/kg bw)	MOS
Hair colour and perms (oxidative and non-oxidative colouration, decolouration)	5.01% (maximum concentration including all decolouration, oxidative and non-oxidative hair colour products)	100 ml = 100 g (this "oxidative" scenario covers the "non-oxidative" scenario wherein 35 ml are used per application)	0.501*	0.16	1,125

Lip care products: Lip balm
The safety assessment of this product type with a maximum aluminium concentration of 0.6% is already covered by the safety assessment of lipsticks in Table 4 (SCCS/1644/22) with a maximum aluminium concentration of 14.62%.

SCCS comment
In line with the recommendations in the SCCS Notes of Guidance (SCCS/1647/22) and argumentation in SCCS/1644/22, for the SED calculation the SCCS will use Scenario 1b for the exposed population. The deterministic calculations for sunscreens will be added, the other product categories can be considered as negligible or covered by the categories assessed in the probabilistic assessment. Note that the maximum aluminium content in sunscreens has been changed with respect to SCCS/1644/22.

3.3 TOXICOLOGICAL EVALUATION

The data related to toxicological evaluation were assessed and commented upon by the SCCS in the previous Opinion (SCCS/1613/19). Only SCCS comments and main conclusions from SCCS/1613/19 are included in this section.

General toxicity

The toxicological evaluation is focused on the toxicity of aluminium compounds relevant to the risk assessment of cosmetic ingredients containing aluminium. There is an extensive body of literature on the health effects and toxicity of aluminium; a number of extensive reviews and authoritative evaluations were published before 2014 (WHO IPCS 1997; Krewski *et al.*, 2007; ATSDR, 2008; EFSA, 2008; FAO/WHO JECFA 2007; Environment Canada & Health Canada 2010; AFSSAPS 2011; FAO/WHO JECFA, 2012; VKM 2013; Willhite *et al*., 2014). For the 2017 SCHEER Opinion on aluminium in toys, a literature search covering the period from 01/01/2008 until 31/01/2017 was performed. The evaluation by JECFA (2011) was based on new data which included a developmental toxicity study specifically evaluating neurobehavioural endpoints (Poirier *et al*., 2011). The LOAELs identified in these studies were consistent with the body of data reviewed previously by other committees; however, the oral developmental toxicity study in rats provided a suitable and robust NOAEL for risk assessment (30 mg/kg bw/day). By applying the standard uncertainty factor of 100 to this NOAEL and considering the bioavailability of aluminium citrate, the JECFA considered it appropriate to revise the PTWI (provisional tolerable weekly intake) upward to 2 mg/kg bw/week. This new data by the JECFA Committee therefore supersedes its earlier Opinions in 2008 and does not contradict the 2008 EFSA Opinion. The SCCS agrees on the NOAEL of 30 mg/kg bw/day used by JECFA for risk assessment.

Irritation/sensitisation

Local dermal effects have been observed when aluminium compounds (10% [w/v] chloride, nitrate) have been applied to the skin of mice, rabbits and pigs over five-day periods (once per day) including epidermal damage, hyperkeratosis, acanthosis and microabcesses (Lansdown, 1973). In this study, these effects were not observed with aluminium acetate, hydroxide or chlorohydrate compounds (SCCS/1626/20 Final version Addendum to the Scientific Opinion SCCS/1613/19 on the safety of aluminium in cosmetic products (lipstick) - Submission II).

Aluminium compounds are widely used in antiperspirants without acute harmful effects to the skin. Some people, however, may be unusually sensitive to topically-applied aluminium compounds. Skin irritation has been reported in human subjects following the application of

aluminium chloride hexahydrate in ethanol used in a high-dose (20% ACH) formulation for the treatment of axillary or palmar hyperhidrosis (excessive sweating) (Ellis and Scurr, 1979; Goh, 1990; Reisfeld & Berliner, 2008) and after use of a crystal deodorant containing alum (Gallego *et al.,* 1999).

Although some high-strength antiperspirants used in hyperhidrosis treatments, using aluminium chloride, have been associated with irritation of the axilla, the long history of cosmetic antiperspirant use would suggest that irritation of the axilla is uncommon. There are several examples of cosmetic product formulations that include raw materials that are irritant in isolation, yet acceptable amongst consumers (e.g. surfactants, menthol).

With respect to skin sensitisation, the SCCS agrees that the available animal studies show that aluminium compounds used in antiperspirants are not skin sensitising. There is limited evidence that aluminium compounds can cause contact allergy in humans. However, taking into account the widespread use of these compounds, the SCCS considers this to be a rare phenomenon.

Mutagenicity/Genotoxicity

The most commonly reported mode of genotoxic action is induction of oxidative stress by aluminium ions. The other suggested MoA is inhibition by Al ions of proteins involved in mitotic spindle function. Hence, an existence of a threshold mechanism for Al ions can be assumed. Considering all the data, the SCCS is of the opinion that under the scenarios of dermal exposure in cosmetics, aluminium is not likely to pose a risk of genotoxic effects.
The SCCS is aware of the request addressed by ECHA for a combined *in vivo* mammalian erythrocyte micronucleus test and an *in vivo* mammalian Comet assay with additional specific investigation on oxidative DNA damage in rats by oral route, using aluminium sulphate. However, the board of appeal of ECHA later annulled[8] the decision to request this new study.

Carcinogenicity

Carcinogenicity studies in animals have been reviewed by the SCCS and were summarised in the Annex of the previous Opinion ((SCCS/1525/14, Revision of 18 June 2014). There was no indication of carcinogenicity at high dietary doses (up to 850 mg Al/kg bw/day) in animal studies, and the SCCS considers that carcinogenicity is not expected at exposure levels that are achieved via cosmetic use.

The new submission comprised only a new exposure assessment, not a new toxicological evaluation. Therefore, only the study selected previously for the safety assessment (Poirier et al, 2011) is reported here in detail, all other studies are summarised and discussed in preceding Opinions, notably in SCCS/1613/19. Only the final SCCS statement taken from discussion of the previous Opinion is reported here for transparency.

Since the last SCCS Opinion 1613/19, two additional papers on the effects of aluminium chloride on chromosomal integrity in mammalian cells have been published, continuing the work of Sappino *et al.* (2012) and Mandriota (2016).
In the study by Mandriota *et al*. (2020) normal mouse mammary epithelial cells after long-term culture in the presence of aluminium chloride formed tumours and metastases when injected into syngeneic and immunocompetent BALB/cByJ mice. As was shown by the authors $AlCl_3$ rapidly increased chromosomal structural abnormalities in the cultured cells.

[8] https://echa.europa.eu/documents/10162/4133890c-5e3f-f63c-d9af-2db6962d698c

In the second study by Tenan *et al.* (2021) in V79 hamster lung fibroblasts exposed to aluminium dose-dependent increases in DNA double strand breaks, and chromosome numerical abnormalities (aneuploidy) as well as arrest in the G2/M phase of the cell cycle, were observed. Additionally, during mitosis, abnormal multipolar mitotic spindles were detected.
Additionally, García-Alegría *et al.,* 2020 investigated aluminium chloride alone and in co-treatment with MNU in female Sprague Dawle rats. They treated rats with 1mL (2000mg/L) of aluminium solution 5 days per week and sampled blood at 5, 10, and 15 days of exposure. They found significant time dependent increase in micronucleus induction as well as DNA damage measured by the comet assay. However, only one concentration of aluminium chloride was used with three exposure time points. In the study of Jalili *et al*., 2020 acute exposure to aluminium chloride induced slight but non-significant oxidative DNA damage in peripheral blood lymphocytes. No increase of micronuclei in either bone marrow cells or in the colon was observed.
Based on analysis of the whole series of 4 articles by the same group as well as additional literature, the SCCS acknowledges that aluminium ions may disturb structural and functional features of chromosomal material in the cells; however, the potential of the ions to induce such effects in the organism after exposure to cosmetic products is still unknown and rather implausible. There is no additional data available to support a link between skin penetration of aluminium and the occurrence of genotoxic effects at relevant exposure conditions. Based on the actual available information, the SCCS is of the opinion that there is no concern for carcinogenicity in the context of use in cosmetics.

Fertility and reproduction toxicity

Poirier *et al.*, 2011, reported a 12-month neuro-developmental toxicity study of aluminium citrate. The study in Sprague-Dawley rats was conducted according to a double-blind, vehicle-controlled randomised design by exposing offspring to aluminium citrate in-utero, through lactation, and then via drinking water post-weaning. The study was conducted according to Good Laboratory Practice (GLP) and was conducted to distinguish between cumulative neurodegenerative and cognitive changes from aberrant neural development alterations. Three dose levels were used: 30, 100, 300 mg Al/kg bw/day, in addition to control groups that received either water or a sodium citrate solution (27.2 g/L) compared to 27.2 g sodium citrate/L in the control group. Aluminium citrate was selected for the study since it is the most soluble and bioavailable aluminium salt. It is also the salt which is likely to be formed readily in the body when absorbed aluminium reacts with endogenous citrate. Pregnant dams (n=20 per group) were exposed to aluminium citrate from gestational day 6 through lactation, and then the offspring (n = 80 per group) were exposed post-weaning until postnatal day 364.
Aluminium citrate was generally well tolerated in the dams at all doses except the high dose (300 mg Al/kg bw/day), which led to diarrhoea in 8 of the treated dams. In high-dosed pups, the main toxic effects were observed in the urinary tract (damage and the formation of calculi (chalky secretions blocking the urinary tract)), resulting in high mortality in the male offspring (see Table 3 below). This caused a differential response in female and male pups. High-dose males were euthanised on study day 98 because of excessive clinical signs (including weight loss, diarrhoea, mild dehydration and poor hair coat).

In the same study, Poirier also evaluated the relative distribution of aluminium following repeated oral administration of various aluminium salts. Sprague–Dawley rats (n= 5 per sex per group) were orally gavaged with formulations of aluminium citrate, sulphate, nitrate, chloride and hydroxide, each delivering a dosage of 30 mg/kg body weight aluminium. Control animals were similarly dosed with deionised water. Animals were dosed daily for either 7 days or 14 days, followed by blood and organ collection. The distribution and concentrations of aluminium present in different tissues and organs were measured by ICP Mass Spectrometry. From this analysis, concentrations in the blood were much lower than those that distributed heterogeneously into other tissues and organs, in both females and males. The authors state

that 'of the few significant differences, concentrations of aluminium were highest for the aluminium citrate treatment.' The authors further conclude from their data that 'bioavailability of the three Al salts (chloride, sulfate and nitrate) and the Al hydroxide looks much lower than that of the Al citrate'.

However, as ^{26}Al was not used as a tracer, it is not possible to know the absolute oral bioavailability of the administered dose.

SCCS comment
Based on the results of this neurodevelopmental toxicity study, the SCCS derives a NOAEL of 30 mg/kg bw/day, which will be used for MoS calculation. This is in line with SCHEER (2017), where the same NOAEL from the same study was used to derive migration limits for Al in toys.

Furthermore, on the basis of available information on solubility (Annex 1 of SCCS/1613/19), the SCCS agrees that aluminium citrate can be regarded as the most bioavailable of the Al salts assessed in this Opinion. Therefore, the derived NOAEL can be regarded as a worst case for all aluminium salts discussed in this Opinion.

3.4 SAFETY EVALUATION (including calculation of the MoS)

The new submission comprised only an update of Al concentrations in products for the dermal aggregate exposure assessment, not a new toxicological evaluation. Therefore, the inhalation exposure assessment, as well as the toxicological assessment, selected NOAEL and point of departure derived in SCCS/1613/19 remain valid.

Based on the results of the neurodevelopmental toxicity study on rats with aluminium citrate (Poirier *et al*., 2011), the SCCS derived a NOAEL of 30 mg aluminium citrate/kg bw/day. After adjustment for the rat oral bioavailability (0.6%) of aluminium citrate (Poirier *et al.,* 2011, Zhou *et al.,* 2008), the systemic exposure at the NOAEL is estimated to be **180 µg Al/kg bw/day**. This value is used as a point of departure for the safety assessment and MoS calculation.

The provided exposure report included an aggregate exposure assessment of all cosmetic categories containing aluminium at maximum levels (Scenario 1b). The respective aggregate estimate is considered valid as the aggregate value for all assessed product categories, for which the main exposure routes are dermal and oral exposure.

The deterministic assessment to aluminium in sunscreens needs to be added to this aggregate assessment.

Table 5: Calculation of aggregate exposure and MoS for aluminium-containing cosmetics

Product type	Systemic Exposure (internal dose) µg Al/kg bw/day	Remarks	MOS based on POD of 180 µg Al/kg bw/day
Dermal from exposure report	0.060	P95, exposed population, Table 4	3006
Dermal sunscreen lotion, deterministic	0.075	Deterministic calculation, see Table 8	2404
Oral from exposure report	0.077	P95, exposed population, Table 4	2343
Inhalation from addendum (respirable + non-respirable)	0.149	P95, exposed population, Table 4	1209
Inhalation for deodorant first 2 min*	0.038		4718
Aggregation across routes and products	**0.399**		**452**

*Correction for high transfer rate between Box 1 and Box 2, SCCS/1644/22

SCCS comment
Under the assumption that approximately 20% of the spray particles are <10 µm for aerosol spray products, the SCCS considers that aluminium is safe for use in antiperspirant and deodorant products (spray and non-spray) and all other product categories at the maximum levels indicated in Table 1 and 2.

3.5 DISCUSSION

Physicochemical properties

From the received information and further literature assessment, it can be concluded that aluminium is not released from talc and is not bioavailable due to exposure to talc. Therefore, body/baby/foot powders containing talc do not need to be considered in the aggregate exposure assessment for aluminium from cosmetics, and the SCCS agrees that a maximum value of 2% aluminium in talc can be considered safe with regard to any risks from aluminium.

Exposure assessment & Toxicokinetics
According to information from Applicant 1, the concentrations for sprays in Table 1 relate to the total formulation of the spray (*i.e.* LiquMakeup Foundation). In the calculations of inhalation exposure for sprayable products, the assumption is made that the percentage of particles/droplets with a diameter of less than 10 µm does not exceed 20% of the total aerosolised particles/droplets. Since the respective data were not made available to the SCCS, this pre-requisite needs to be captured in the conclusion.

The SCCS follows the argumentation of Applicant 2 that aluminium in talc can be considered as not bioavailable. Therefore, the SCCS agrees that the aluminium concentrations in talc used in cosmetics may be up to 2%. Consequently, the entry for talc from Applicant 1 was deleted in Table 2 above and replaced by the conclusions based on the data shared by Applicant 2.

A dermal absorption percentage of 0.00192% was used in the presented exposure calculation. This is considered a valid absorption value, which was derived from a study with an antiperspirant. Due to occlusion and formulation characteristics of antiperspirants, the dermal absorption for antiperspirants is considered to be a conservative value that is also valid for the other cosmetic products addressed in this Opinion.

The SCCS considers that oral bioavailability of 0.1% is an appropriate value for use in risk assessment for indirect ingestion after removal from the upper respiratory tract by the mucociliary elevator.

Regarding inhalation, as reported in the SCCS/1613/19, a conservative value for aluminium uptake by the lung of 3% is an appropriate value for use in risk assessment. From the upper respiratory tract, no data on bioavailability is available, but since mucociliary clearance will lead to expectorate or swallowing of the Al trapped in that part of the body, intestinal resorption values of 0.1 or 0.3% can be used (EFSA, 2008).

Compared to SCCS/1644/22, concentration values in products have been updated in the new probabilistic aggregate exposure assessment: Applicant 1 has now used higher concentrations for the product categories Bar Soap, Hair Styling, Liquid Hand Soap and LiquMakeup Foundation in the new Scenario 1b as well as more conservative inhalation parameters.

In line with the recommendations in the SCCS Notes of Guidance (SCCS/1647/22) and argumentation in SCCS/1644/22, for the SED calculation the SCCS will use Scenario 1b for the exposed population. The deterministic calculations for sunscreens will be added, the other product categories can be considered as negligible or covered by the categories assessed in the probabilistic assessment. Note that the maximum aluminium content in sunscreens has been changed with respect to SCCS/1644/22.

Toxicological Evaluation

Based on the results of this neurodevelopmental toxicity study, the SCCS derives a NOAEL of 30 mg/kg bw/day, which will be used for MoS calculation. This is in line with SCHEER (2017), where the same NOAEL from the same study was used to derive migration limits for Al in toys.

Furthermore, on the basis of available information on solubility (Annex 1 of SCCS/1613/19), the SCCS agrees that aluminium citrate can be regarded as the most bioavailable of the Al salts assessed in this Opinion. Therefore, the derived NOAEL can be regarded as a worst case for all aluminium salts discussed in this Opinion.

Safety Evaluation

Under the assumption that approximately 20% of the spray particles are <10 µm for aerosol spray products, the SCCS considers that aluminium is safe for use in antiperspirant and deodorant products (spray and non-spray) and all other product categories at the maximum levels indicated in Table 1 and 2.

4. CONCLUSION

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.*

   The SCCS considers that aluminium compounds are safe when used:

   - in non-sprayable product categories at the maximum levels indicated in Tables 1 and 2.

   - in sprayable products, at the maximum levels for the total formulation (*i.e.* including propellant) indicated in Table 1, 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. Since the Applicant's data submission indicated that aluminium is not used in sunscreen aerosol sprays, this Opinion does not cover sunscreen aerosol sprays.

   - the SCCS considers that aluminium in talc is not bioavailable. Therefore, talc with aluminium-content of up to 2% may be used in cosmetic products.

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?*

   As mentioned in Opinion SCCS/1644/22, aluminium does not belong to substances classified as CMR 1A or 1B, so that only exposure from cosmetic uses was considered in this safety assessment with the exposure assessment based on maximum use levels for cosmetic ingredients. However, as evaluated in SCCS/1644/22, aggregated exposure from cosmetics and food may exceed safe limits for consumers at the highest exposure ranges.

   It needs to be noted that this Opinion specifically covers the risk to consumers from exposure to aluminium from cosmetic products. As such, this Opinion does not address the safety of the use of talc in cosmetic products beyond the safety of the aluminium content in talc.

   This Opinion does not apply to nano forms of aluminium for which a separate specific safety assessment would be needed.

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7. GLOSSARY OF TERMS

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8. LIST OF ABBREVIATIONS

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