Scientific Committee on Consumer Safety

SCCS

ADDENDUM

to the scientific opinion SCCS/1613/19 on the safety of aluminium in cosmetic products (lipstick) - Submission II

The SCCS adopted this document
at its plenary meeting on 30-31 March 2021

ACKNOWLEDGMENTS

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This Opinion has been subject to a commenting period of eight weeks after its initial publication (from 15 December 2020 until 15 February 2021). Comments received during this time period are considered by the SCCS. The final version has not been amended as no change occurred.

1. ABSTRACT

The SCCS concludes the following:

1. *In light of the new data provided, does the SCCS consider Aluminium safe when used in lipsticks up to a maximum concentration of 14%? In the event that the estimated exposure to Aluminium from lipsticks of cosmetic products is found to be of concern, SCCS is asked to recommend safe concentration limits.*

In the light of the new data provided, the SCCS considers that the use of aluminium compounds is safe at the following equivalent aluminium concentrations up to:

· 6.25% in non-spray deodorants or non-spray antiperspirants
· 10.60% in spray deodorants or spray antiperspirants
· 2.65% in toothpaste and
· 14% in lipstick

2. *Does the SCCS have any further scientific concerns regarding the use of Aluminium substances in cosmetic products taking into account the newly submitted information on aggregate exposure from cosmetics?*

The SCCS considers that the systemic exposure to aluminium via daily applications of cosmetic products does not add significantly to the systemic body burden of aluminium from other sources. Exposure to aluminium may also occur from sources other than cosmetic products, and a major source of aluminium in the population is the diet. This assessment has not taken into account the daily dietary intake of aluminium.

Keywords: SCCS, scientific opinion, aluminium, addendum, lipstick, Regulation 1223/2009

Opinion to be cited as: 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

About the Scientific Committees

Two independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.
These Committees are: the Scientific Committee on Consumer Safety (SCCS) and the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) and they are made up of scientists appointed in their personal capacity.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCCS

The Committee shall provide Opinions on questions concerning health and safety risks (notably chemical, biological, mechanical and other physical risks) of non-food consumer products (for example cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products such as detergents, etc.) and services (for example: tattooing, artificial sun tanning, etc.).

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PDF ISSN 1831-4767 ISBN 978-92-76-55211-6 doi:10.2875/59197 EW-AQ-22-019-EN-N

https://health.ec.europa.eu/scientific-committees/scientific-committee-consumer-safety-sccs_en

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2. MANDATE FROM THE EUROPEAN COMMISSION

Background

Following the dossier submission on the safety of aluminium in cosmetic products, the SCCS in its corresponding opinion SCCS/1613/19, has concluded that: *'the use of aluminium compounds is safe at the following equivalent aluminium concentrations up to:*

6.25% in non-spray deodorants or non-spray antiperspirants
10.60% in spray deodorants or spray antiperspirants
2.65% in toothpaste and
0.77% in lipstick

The current request for an Addendum is based on the recently identified mistake in the applicant's previous submission concerning the maximum % concentration of aluminium in lipsticks. The current submission includes in particular additional data and considerations on the MoS calculation and aggregate exposure.

Terms of reference

1. *In light of the new data provided, does the SCCS consider Aluminium safe when used in lipsticks up to a maximum concentration of 14%? In the event that the estimated exposure to Aluminium from lipsticks of cosmetic products is found to be of concern, SCCS is asked to recommend safe concentration limits.*

2. *Does the SCCS have any further scientific concerns regarding the use of Aluminium substances in cosmetic products taking into account the newly submitted information on aggregate exposure from cosmetics?*

3. OPINION

3.1 Chemical and Physical Specifications

Physicochemical properties of aluminium compounds used as cosmetic ingredients are summarised in Annex I of the previous opinion (SCCS/1613/19).

3.2 Function and uses

Taken from the previous opinion (SCCS/1613/19).

<u>Antiperspirants</u>

Aluminium salts in antiperspirants, such as aluminium chlorohydrate, form insoluble aluminium hydroxide polymer gel plugs within sweat ducts to temporarily prevent sweat reaching the surface of the skin. These substances are soluble at very low pH in the formulation; however, once applied on the skin they form chemically inert complexes with basic components of sweat and skin. The relatively high molecular weight of the compounds, low 'Log P' and high positive charge limits the potential for skin penetration through the *stratum corneum*. Moreover, absorption across the skin is further minimised by the formation of protein complexes in the outermost layers of the *stratum corneum* (Hostynek, 2003). These chemical properties limit the systemic delivery of aluminium via the intake skin.

<u>Lipsticks</u>

Aluminium colloidal colorant 'lakes' are mainly used in lipsticks. Colloidal colourants are prepared under aqueous conditions by reacting aluminium oxide with the organic pigments in order to make them insoluble. Aluminium oxide is usually freshly prepared by reacting aluminium sulphate or aluminium chloride with sodium carbonate or sodium bicarbonate or aqueous ammonia. Due to the complex molecular structures and high molecular weights of organic lakes, the aluminium represents only a small part of the weight of the raw material of which the extractable (bioaccessible) part will represent only a fraction.

<u>Toothpastes</u>

Insoluble minerals are used in toothpastes mainly to act as mild abrasives and to provide shine/gloss benefit through the polishing of the enamel. They are also used to improve rheology in striped toothpastes. Toothpastes may also contain aluminium colloidal colourant "lakes" and pigments.

3.3 Toxicological evaluation

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

3.3.1 Acute toxicity

3.3.1.1 Acute oral toxicity

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SCCS comment
The acute oral toxicity of those aluminium compounds for which data are available (bromide, nitrate, chloride and sulfate) is moderate to low, with LD_{50} values ranging from 162 to 750 mg Al/kg bw in rats, and from 164 to 980 mg Al/kg bw in mice, depending on the aluminium compound (EFSA, 2008).

3.3.1.2 Acute dermal toxicity

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3.3.1.3 Acute inhalation toxicity

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SCCS comment
The acute inhalation toxicity of aluminium oxide seems to be up to 1,000 mg Al/m^3 in male Fischer 344 rats (Thomson et al., 1986).

3.3.1.4 Acute intraperitoneal toxicity

/

3.3.2 Irritation and corrosivity

3.3.2.1 Skin irritation

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SCCS comment
The SCCS agrees with the applicant that use concentrations of aluminium compounds in antiperspirants (at doses up to 20% ACH) will not lead to skin irritation in consumers.

3.3.2.2 Mucous membrane irritation / Eye irritation

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3.3.3 Skin sensitisation and dermatitis

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SCCS comment
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.

3.3.4 Dermal / percutaneous absorption

3.3.4.1 *In vitro* animal skin absorption studies

The data related to this part were assessed and commented upon by the SCCS in the previous Opinion (SCCS/1525/14, Revision of 18 June 2014).

3.3.4.2 Animal skin absorption studies

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3.3.4.3 *In vitro* human ski absorption studies

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3.3.4.4 *In vivo* human skin absorption study – single dose

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3.3.4.5 *In vivo* human skin absorption study – single and repeat dose, in use concentrations

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SCCS conclusion

The SCCS agrees that dermal bioavailability of 0.00052% is an appropriate value for use in risk assessment.

3.3.5 Repeated-dose toxicity

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SCCS comments on Sub-chronic Rat/ dog oral Studies
When orally administered to rats, aluminium compounds (including aluminium nitrate, aluminium sulfate and potassium aluminium sulfate) have caused various effects, including decreased body weight gain and mild histopathological changes in the spleen, kidneys and livers of rats (104 mg Al/kg bw/day) and dogs (88-93 mg Al/kg bw/day) after subchronic oral exposure. Effects on nerve cells, testes, bone and stomach have been reported at higher doses. Severity of effects increased with dose.

SCCS comments on repeated-dose inhalation toxicity
Neurological examinations in the Steinhagen et al., 1978, publication have been limited to measurement of brain weight and/or histopathology of the brain; no function tests were performed.
The SCCS is of the opinion that the available information does not support concerns regarding potential toxicity of aluminium compounds by inhalation. The lung effects observed in humans and animals are suggestive of particle overload.

Repeated-dose dermal toxicity
There are no repeat dose toxicology studies available via the dermal route of exposure.

3.3.6 Mutagenicity / Genotoxicity

3.3.6.1 Mutagenicity / Genotoxicity *in vitro*

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3.3.6.2 Mutagenicity / Genotoxicity *in vivo*

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SCCS comments
Considering all the available evidence, the SCCS is of the opinion that aluminium is not likely to pose a risk of systemic genotoxic effects through the dermal exposure from cosmetics use.

3.3.7 Carcinogenicity

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SCCS comment
The SCCS is of the opinion that based on the available information, aluminium from aluminium compounds is not considered to have potential carcinogenicity.

3.3.8 Reproductive toxicity

3.3.8.1 Fertility and reproductive toxicity

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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.

3.3.8.2 Two generation reproduction toxicity

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3.3.9 Toxicokinetics

3.3.9.1 Toxicokinetics in laboratory animals

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3.3.9.2 Toxicokinetics in humans

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SCCS comments
The SCCS considers that oral bioavailability of 0.1% is an appropriate value for use in risk assessment.

Taken together, all available data suggest that absorption of aluminium from lung deposits into 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).
Human and animal studies cited in the current Opinion suggest that the urinary excretion of aluminium is multiphasic, and the TNO study 2019 has shown that after a single IV injection of ^{26}Al citrate in healthy subjects, more than 50% of the Al administered is excreted in the urine within the first 24h. It is known that the remaining amounts of ^{26}Al are eliminated extremely slowly (Priest, 2004).

3.3.10 Photo-induced toxicity

3.3.10.1 Phototoxicity / photo-irritation and photosensitisation

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3.3.10.2 Photomutagenicity / photoclastogenicity

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3.3.11 Human data

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3.3.12 Special investigations

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3.3.13 Consumer Exposure assessment

Dermal exposure

Antiperspirants

Cosmetics Europe data show that average (median) consumers apply 0.82 g/day of non-spray deodorant/antiperspirant, rising to 1.5 g/day for 90th percentile high-level consumers (Hall et al., 2007). Following the SCCS Notes of Guidance (10th Revision), the 90th percentile product exposure for non-spray deodorants/antiperspirants can be expressed on a bodyweight basis as 22.08 mg product/kg bw/day (SCCS/1602/18).

Thus, at 6.25% aluminium (from aluminium chlorohydrate or ACH) for a high-performing non-spray antiperspirant, assuming exposure at 22.08 mg product/kg bw/day, the dermal exposure to aluminium would be 1.38 mg aluminium chlorohydrate /kg bw/day (0.0625 x 22.08 mg/kg/day). Using the dermal fraction absorbed value of 0.00052%, from the human clinical TNO Study 2, where ACH was applied under in-use conditions in females, the systemic exposure of aluminium via dermal application of non-spray antiperspirants is 0.007 µg/kg bw/day.

This is expressed mathematically in the following calculation for systemic exposure dose (SED) as per the SCCS 10th Notes of Guidance (SCCS/1602/18).

$$SED = E_{product} \times \frac{C}{100} \times \frac{DA_p}{100}$$

Where:
SED (mg/kg bw/day) Systemic Exposure Dose

$E_{product}$ (mg/kg bw/day) Estimated daily exposure to a cosmetic product per kg body weight, based on the amount applied and the frequency of application (for calculated relative daily exposure levels for different cosmetic product types (SCCS/1602/18).

C (%) Concentration of the substance under study in the finished cosmetic product on the application site

DAp (%) Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions

Therefore, for non-spray antiperspirants:
SED = 22.08 (mg/kg bw/day) x 6.25/100 x 0.00052/100 = 0.007 µg/kg bw/day

The mean cumulative 'recovery' in faecal data was 0.0014%. When the SCCS took into account the amount of radiolabelled aluminium found in urine and faeces, a value of dermal bioavailability of 0.00192% could be estimated (0.00052% +0.0014%).
Therefore, for non-spray antiperspirants, taking account the amount of radiolabelled aluminium found in urine and faeces, for the estimations of dermal bioavailability was:
SED = 22.08 (mg/kg bw/day) x 6.25/100 x 0.00192/100 = 0.0265 µg/kg bw/day

Using the dermal fraction absorbed value of 0.00192% from the human clinical study, where ACH was applied under in use conditions in females, the systemic exposure of aluminium via dermal application of non-spray antiperspirants is 0.0265 µg/kg bw/day.

For spray antiperspirants, which are generally non-ethanol based formulations due to incompatibility of antiperspirant actives and alcoholic formulations, dermal product exposure is 10 mg product/kg bw/day (SCCS, 2018). This product exposure value excludes the propellant (Steiling et al., 2012). Since aluminium is 2.86% of the full Compressed 2 formulation, aluminium would be 10.6% of the non-volatile fraction. Therefore, 1.06 mg/kg bw/day of aluminium is applied to the skin (10.6% of 10 mg/kg bw/day). Taking the dermal absorption of 0.00052% from the second TNO skin absorption study, the associated systemic exposure via the skin would be 0.006 µg/kg bw/day (0.00052% of 1.06 mg/kg bw/day).

Therefore, for spray antiperspirant products:

SED = 10 (mg/kg bw/day) x 10.6/100 Al x 0.00052/100 = 0.006 µg/kg bw/day

Using the dermal fraction absorbed value of 0.00052% from the human clinical study, where ACH was applied under in use conditions in females, the systemic exposure of aluminium via dermal application of spray antiperspirants is 0.006 µg/kg bw/day.

The mean cumulative 'recovery' in faecal data was 0.0014%. When the SCCS took into account the amount of radiolabelled aluminium found in urine and faeces, a value of dermal bioavailability of 0.00192% could be estimated (0.00052% +0.0014%).
Therefore, for spray antiperspirants, taking account the amount of radiolabelled aluminium found in urine and faeces, for the estimations of dermal bioavailability was:

SED = 10 (mg/kg bw/day) x 10.6/100 Al x 0.00192/100 = 0.0204 µg/kg bw/day

Using the dermal fraction absorbed value of 0.00192% from the human clinical study, where ACH was applied under in use conditions in females, the systemic exposure of aluminium via dermal application of spray antiperspirants is 0.020 µg/kg bw/day.

The calculated values above of SED from antiperspirants containing 6% ACH are used in the safety evaluations.

Oral exposure

<u>Lipsticks</u>

From the new applicant's submissions:

Based on a survey of Cosmetic Europe members, lipsticks currently on the EU market contain a maximum level of 14% aluminium which comes from colourant lakes and other aluminium containing ingredients such as minerals. Thus, the daily intake would be 14% x 0.9 mg product/kg bw/day = 0.126 mg Al/kg/day. If one assumes the bioaccessible fraction is 7%, then the bioaccessible amount is 0.0088 mg Al/kg/day in soluble form. The bioavailability of aluminium from insoluble aluminium-containing material is considered to be about 0.1% (EFSA, 2008), therefore 0.009 µg Al/kg bw/day maximally could be systemically bioavailable.

The value of 0.009 µg/kg bw/day will be taken forward into the safety evaluation. This is based upon the maximum level of aluminium in lipsticks according to a survey of Cosmetics Europe, with the conservative assumption of complete 100% ingestion of applied product and the conservative assumption (based upon data) of 7% bioaccessibility, which was calculated using lipstick ingredients, and is expected to be even lower from a waxy lipstick product matrix.

SCCS comments

The SCCS notes that so far bio-accessibility testing has mainly been applied in the context of soil contamination and uncertainties exist whether and to which extent bioaccessibility would reflect bioavailability.

Furthermore, from the literature available on bio-accessibility testing, large inter laboratories variation was reported and so far no internationally accepted OECD guideline exists.

Based on these uncertainties, the SCCS prefers using a worst-case approach to calculate systemic aluminium exposure from lipsticks (i.e. that 100% of the aluminium content in lipstick would be available for absorption).

The daily intake would be 14% x 0.9mg product/kg bw/day = 0.126 mg Al/kg/day. Assuming a bio-accessible fraction of 100%, the bio-accessible amount is 0.126 mg Al/kg/day in soluble form. The bioavailability of aluminium from insoluble aluminium-containing material is considered to be about 0.1% (EFSA, 2008), therefore 0.126 µg Al/kg bw/day maximally could be systemically bioavailable.

Therefore, the value of 0.126 µg/kg bw/day will be taken forward for the safety evaluation.

Taken from the previous Opinion (SCCS/1613/19).

<u>Toothpaste</u>

Using the SCCS Notes of Guidance 10th revision (SCCS/1602/18) for toothpaste, the estimated daily exposure is 2.75 g/day for the 90th percentile high level consumer and it is assumed that 5% of the toothpaste used to clean teeth is swallowed, resulting in 2.16 mg product/kg bw/day for a 60kg adult (SCCS, 2018).
Based on a survey of Cosmetic Europe members in 2013, toothpaste currently on the EU market contains a maximum level of 5% aluminium oxide (equivalent to 2.65% aluminium). Thus of 2.16 mg product/kg bw/day, 57µg Al/kg bw/day would be ingested.
Using an oral bioavailability value for aluminium oxide of 0.1%, the systemic exposure dose for adults (60 kg) is calculated to be 0.057 µg Al/kg bw/day. This value is used in the safety evaluation.

Inhalation exposure

Meech et al., 2011, used an experimental measure of lung exposure to assess the intake from inhalation exposure. The same values used in risk assessment are:
Respirable in deep lung = 0.00781 µg/kg bw/day.
Respirable dose deposited in upper respiratory tract = 0.00234 µg/kg bw/day.
Non-respirable dose = 0.000432 µg/kg bw/day.

The methodology used in the 2016 dossier next to the respirable dose method has also been recently published in Schwarz *et al*., 2018.

3.4 SAFETY EVALUATION (including calculation of the MoS)

The Margins of Safety for each of the three cosmetic product types, antiperspirants, lipstick and toothpaste are presented in Table 1 (considering non-spray antiperspirants) and Table 6a (considering spray antiperspirants). Each product is considered individually in terms of the MoS for systemic effects.
A total systemic body burden has been calculated assuming that all three product types are used on the same day.

Taking the NOAEL of 30 mg aluminium citrate/kg bw/day from the neurodevelopmental rat study (Poirier et al., 2011) and adjusting by 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.

Table 1: Overall margin of safety calculations for antiperspirant non-spray products (dermal exposure only), lipstick and toothpaste and a total body burden calculation to account for potential simultaneous exposure.

Product type	**Systemic Exposure (internal dose) µg Al/kg bw/day**	**MoS (based on an internal dose POD of 180 µg Al/kg bw/day)**
Dermal exposure		
Antiperspirant (roll-on/stick)	0.007	25,714
Oral exposure		
Lipstick	0.126	1428
Toothpaste	0.057	3,158
Total Systemic Body Burden	0.19	947

When the SCCS took into account the amount of radiolabelled aluminium found in urine and faeces for the estimations of dermal absorption (e.g. a dermal absorption of 0.00192%), it did not alter the overall safety assessment (Table 2):

Table 2: Overall margin of safety calculations for antiperspirant non-spray products (dermal exposure only), lipstick and toothpaste and a total body burden calculation to account for potential simultaneous exposure and considering dermal absorption of 0.00192%.

Product type	**Systemic Exposure (internal dose) µg Al/kg bw/day**	**MoS (based on an internal dose POD of 180 µg Al/kg bw/day)**
Dermal exposure		
Antiperspirant (roll-on/stick)	0.0265	6,792

Oral exposure		
Lipstick	0.126	1428
Toothpaste	0.057	3,158
Total Systemic Body Burden	0.2095	859

Table 3: Overall margin of safety calculations for antiperspirant spray products (dermal and inhalation exposure), lipstick and toothpaste and a total body burden calculation to account for potential simultaneous exposure.

Product type	**Systemic Exposure (internal dose) µg Al/kg bw/day**	**MOS (based on an internal dose POD of 180 µg Al/kg bw/day)**
Dermal exposure		
Antiperspirant (spray)	0.006	30,000
Oral exposure		
Lipstick	0.126	1428
Toothpaste	0.057	3158
Inhalation exposure (systemic)		
Antiperspirant sprays/aerosols (Respirable in deep lung)	0.00781	23,047
Antiperspirant sprays/aerosols (Respirable deposited in upper respiratory tract)	0.00234	76,923
Antiperspirant sprays/aerosols (Non-respirable)	0.000432	416,667
Total Systemic Body Burden	0.1996	901

When the SCCS took into account the amount of radiolabelled aluminium found in urine and faeces for the estimations of dermal absorption (e.g. a dermal absorption of 0.00192%), it did not alter the overall safety assessment (Table 4):

Table 4: Overall margin of safety calculations for antiperspirant spray products (dermal and inhalation exposure), lipstick and toothpaste and a total body burden calculation to account for potential simultaneous exposure and considering dermal absorption of 0.00192%.

Product type	**Systemic Exposure (internal dose) µg Al/kg bw/day**	**MOS (based on an internal dose POD of 180 µg Al/kg bw/day)**
Dermal exposure		
Antiperspirant (spray)	0.0204	8,823
Oral exposure		
Lipstick	0.126	1428
Toothpaste	0.057	3158
Inhalation exposure (systemic)		
Antiperspirant	0.00781	23,047

sprays/aerosols (Respirable in deep lung)		
Antiperspirant sprays/aerosols (Respirable deposited in upper respiratory tract)	0.00234	76,923
Antiperspirant sprays/aerosols (Non-respirable)	0.000432	416,667
Total Systemic Body Burden	0.2140	841

3.5 DISCUSSION

Function and uses

A variety of aluminium salts, complexes and mineral compounds are used as cosmetics ingredients, e.g. as antiperspirants, toothpaste or in lipstick (see Annex I in (SCCS/1613/19).

Physicochemical properties

Physicochemical properties of aluminium compounds used as cosmetic ingredients are given in Annex I: in this Annex the correct CAS No for MICA containing aluminium is 12001-26-2.

General toxicity

The toxicological evaluation is focused on the toxicity of aluminium compounds relevant to the risk assessment of cosmetics 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 the 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 seen with aluminium acetate, hydroxide or chlorohydrate compounds.

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).
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.

Dermal absorption
In the new study described in the Opinion, the Applicant provided an estimate of the aluminium bioavailability after dermal exposure. The SCCS agrees that a dermal absorption value of 0.00052% is an appropriate value to use in risk assessment.

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 combined *in vivo* mammalian erythrocyte micronucleus test and *in vivo* mammalian Comet assay with additional specific investigation on oxidative DNA damage in rats by oral route, using aluminium sulphate.

Carcinogenicity
Carcinogenicity studies in animals have been reviewed by the SCCS and are 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.

Toxicokinetics
Aluminium compounds present in food and drinking water are poorly absorbed through the gastrointestinal tract in animals and humans.

Several small scale human studies estimated aluminium absorption efficiencies of 0.07–0.39% following administration of a single dose of the radionuclide aluminium-26 (^{26}Al) in drinking water (Hohl et al., 1994; Priest et al., 1998; Stauber et al., 1999; Steinhausen et al., 2004). Fractional absorption was estimated by measuring aluminium levels in urine; it is likely that most of these studies (with the exception of Stauber et al., 1999) underestimated gastrointestinal absorption because the amount of aluminium retained in tissues or excreted by non-renal routes was not factored into the absorption calculations. Several animal studies also utilised ^{26}Al to estimate aluminium bioavailability from drinking water. When aluminium levels in urine and bone were considered, absorption rates of 0.04–0.06% were estimated in rats (Drueke et al., 1997; Jouhanneau et al., 1993); when liver and brain aluminium levels were also considered, an absorption rate of 0.1% was estimated (Jouhanneau et al., 1997). Another study that utilised a comparison of the area under the plasma aluminium concentration-time curve after oral and intravenous administration of ^{26}Al estimated an oral aluminium bioavailability of 0.28% (Yokel et al., 2001).

Two human studies examined the bioavailability of aluminium in the diet. An absorption efficiency of 0.28–0.76% was estimated in subjects ingesting 3 mg aluminium lactate/day (0.04 mg Al/kg/day) or 4.6 mg aluminium citrate/day (0.07 mg Al/kg/day) (Greger and Baier 1983; Stauber et al., 1999). When 125 mg Al/day (1.8 mg Al/kg/day) as aluminium lactate in fruit juice was added to the diet, aluminium absorption decreased to 0.094% (Greger and Baier, 1983). Yokel and McNamara (2001) suggested that the bioavailability of aluminium from the diet is 0.1% based on daily urinary excretion levels of 4–12 μg and average aluminium intake by adults in the United States of 5,000–10,000 μg/day.
Considering the available human and animal data as discussed above, it is likely that the oral absorption of aluminium can vary up to 10-fold, based on the chemical form alone. Although bioavailability appears to generally parallel to water solubility, insufficient data are available to allow direct extrapolation from solubility in water to bioavailability. Additionally, due to the available dietary ligands, such as citrate, lactate, and other organic carboxylic acid complexing agents, the bioavailability of any particular aluminium compound can be markedly different depending on if someone's stomach was full or empty.

Aluminium retention in the body
The SCCS notes that aluminium has several half-lives corresponding to the different distribution phases preceding the terminal elimination half-life. The terminal half-life of aluminium is not known.
Human and animal studies cited in the current Opinion suggest that the urinary excretion of aluminium is biphasic and have shown that after a single IV injection of ^{26}Al citrate in healthy subjects, more than 50% of the Al administered is excreted in the urine within the first 24h. In conclusion, even if aluminium accumulation cannot be ruled out after dermal exposure, any significant accumulation in the body is unlikely following daily use of cosmetic products.

Human data
The SCCS considers that aluminium is a known neurotoxicant in animals. Circumstantial evidence has linked this metal with several neurodegenerative disorders, like Alzheimer's disease (Miu and Benga, 2006; Percy et al., 2011), Parkinson's diseases (Oyanagi, 2005) and other chronic neurodegenerative diseases (Bondy, 2010), but no causal relationship has yet been proven.

4. CONCLUSION

1. *In light of the new data provided, does the SCCS consider Aluminium safe when used in lipsticks up to a maximum concentration of 14%? In the event that the estimated exposure to Aluminium from lipsticks of cosmetic products is found to be of concern, SCCS is asked to recommend safe concentration limits.*

In the light of the new data provided, the SCCS considers that the use of aluminium compounds is safe at the following equivalent aluminium concentrations up to:

· 6.25% in non-spray deodorants or non-spray antiperspirants
· 10.60% in spray deodorants or spray antiperspirants
· 2.65% in toothpaste and
· 14% in lipstick

2. *Does the SCCS have any further scientific concerns regarding the use of Aluminium substances in cosmetic products taking into account the newly submitted information on aggregate exposure from cosmetics?*

The SCCS considers that the systemic exposure to aluminium via daily applications of cosmetic products does not add significantly to the systemic body burden of aluminium from other sources. Exposure to aluminium may also occur from sources other than cosmetic products, and a major source of aluminium in the population is the diet. This assessment has not taken into account the daily dietary intake of aluminium.

5. MINORITY OPINION

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7. GLOSSARY OF TERMS

See SCCS/1628/21, 11th Revision of the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation – from page 181

8. LIST OF ABBREVIATIONS

See SCCS/1628/21, 11th Revision of the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation – from page 181

<u>ANNEX 1:</u> Cosmetics Ingredients containing aluminium

Aluminium salts, complexes and mineral compounds used as cosmetics ingredients

Chemical Name	INCI Name	CAS Number	Common synonyms	Chemical formula	Mol Wt	LogP	Water solubility (g/l)	Physical Form
Simple Inorganic Salts								
Aluminium Sulphate	Aluminium sulfate	10043-01-3	Alum; E520	$Al_2(SO_4^{2-})_3$	342.15	-	soluble	white crystal/powder
Aluminium Potassium Sulphate	Potassium alum	10043-67-1	Potassium alum; E555	$KAl(SO_4^{2-})_2$	258.19	-	slightly soluble	white powder
Aluminium Ammonium Sulphate	Ammonium alum	7784-25-0	Ammonium alum	$NH_4Al_2(SO_4^{2-})_2$	237.15	-1.031 (est)	very soluble	white powder
Simple Organic Salts								
Aluminium Lactate	Aluminium lactate	18917-91-4	Aluctyl	$Al[CH_3(OH)CO_2^-]_3$	294.19	-2.43 to -1.90	soluble	white/yellow powder
Aluminium Citrate	-	31142-56-0	Aluminium citrate	$(NH_4^+)_5[Al_3(H_{-1}Cit)_3(OH)(H_2O)[NO_3^-]\bullet 6H_2O$	216.08	-1.48	soluble	white powder
Aluminium Glycinate	Dihydroxyaluminium aminoacetate	13682-92-3	Dihydroxy aluminium aminoacetate	$Al(OH)(CH_2NH_2CO_2^{2-})$	135.05	-1.85	insoluble	fine powder
Aluminium Benzoate	Aluminium benzoate	555-32-8	Aluminium tribenzoate	$Al(C_7H_6O_2^-)_3$	390.32	1.895 /3.923 10	very slightly soluble	white crystal/powder
Chlorohydrates								
Aluminium chloride hexahydrate	-	7784-13-6	Hydrated aluminium chloride	$AlCl_3\bullet 6H_2O$	241.43	-	soluble	colorless/ white
Aluminium chlorohydrate (ACH)	-	1327-41-9	aluminium hydroxychloride , aluminium chlorhydroxide	$Al_2Cl(OH)_5$	138.50	-	soluble	-
Aluminium chlorohydrate 80% solid	-	-	-	-	-	-	-	-
Aluminium sesquichloro-hydrate	-	173763-15-0	-	$Al_2(OH)_yCl_z$ x nH_2O (z=1,1 1,3, y=6x)	-	-	-	-
Zirconium - aluminium - glycine complexes (ZAG)								
Aluminium Zirconium Trichlorohydrate Glycine	Aluminium zirconium trichlorohydrex	134375-99-8	Aluminium zirconium trichlorohydrex	$Al_8Zr(OH)_{13}Cl_3.xH_2O$ with glycerin	-	-	soluble	white powder

	gly		gly					
Aluminium Zirconium Tetrachlorohydrate Glycine	Aluminium zirconium tetrachlorohydrex gly	134910-86-4	Aluminium zirconium tetrachlorohydrex gly	$Al_4Zr(OH)_{12}Cl_4$ Gly x nH_2O	-	-	soluble	white powder
Aluminium Zirconium Octachlorohydrate Glycine	Aluminium zirconium octachlorohydrex gly	174514-58-0	Aluminium zirconium octachlorohydrex Gly; Complex reaction product obtained from the reaction of aluminium zirconium octachlorohydrate (Al8Zr(OH)20Cl8 .xH2O) and glycine	$C_2H_8AlClNO_4Zr^{+5}$	263.75	-	-	white powder
Zirconium-aluminium complexes (ZACH)								
Aluminium Zirconium Tetrachlorohydrate	-	-	-	-	-	-	-	-
Aluminium Zirconium Pentachlorohydrate	-	173762-83-9	-	$AlCl_5ZrH_2$	-	-	-	-
Water insoluble Minerals, Glasses and Clays								
Aluminium hydroxide (Gibbsite)	Aluminium hydroxide	21645-51-2	Aldrox; alumina hydrate; gibbsite	$Al(OH)_3$	78.00	-	insoluble	white amorphous powder
Aluminium magnesium hydroxide	-	39366-43-3	Aluminium magnesium pentahydroxide	AlH_5MgO_5	136.32	-	-	-
Aluminium oxide (Alumina, aluminium sesquioxide)	Alumina	1344-28-1	-	Al_2O_3	101.96	-	insoluble	white crystal/powder
Perlite (Volcanic Glass, 12–15% Al2O3)	Perlite	93763-70-3/ 130885-09-5	Sodium Potassium Aluminium Silicate	Natural volcanic glass with higher amounts of water (2-5%). White to light gray, glassy.	-	-	insoluble	white powder
Bentonite (volcanic ash derived clay; E 558)	Bentonite	1302-78-9	Taylorite; Wilkinite; Alumino silicate; Sodium	$Al_2H_2O_6Si$	180.06	-	insoluble	gray powder

			montmorillonite ;					
Hectorite (Na0:3(Mg; Li)3Si4O10(OH)2; 0.6% Al2O3)	Hectorite	12173-47-6	Hectorite (clay mineral)	$Na_{0.3}(Mg,Li)_3Si_4O_{10}(OH)_2$	283.25	-	insoluble	white powder
Synthetic Sapphire	Synthetic Sapphire	-	-	$Al_2O_3 + Cr_2O_3$		-	insoluble	
Cobalt Aluminium Oxide	Cobalt Aluminium Oxide	1345-16-0	Aluminium cobalt oxide; C.I. Pigment Blue 28; Cobalt aluminate blue spinel , C.I.77346	Al_2CoO_4	176.89	-	insoluble (< 0.1 mg/L)	blue powder
Aluminium silicate (Kaolin and clay minerals; E 559; CI 77004)	Kaolin	1332-58-7	-	$Al_2Si_2O_5(OH)_4$	259.76	-	insoluble	white powder
Kaolin (Al2Si2O5(OH)4; Clay silicate mineral)	Kaolin	1332-58-7	-	$Al_2Si_2O_5(OH)_4$	259.76	-	insoluble	white powder
Topaz (Silicate of aluminium and fluorine; Al2SiO4(F,OH)2)	Topaz	1302-59-6	Pycnite	$Al_2SiO_4(F,OH)_2$	182.25	-	-	-
Aluminium calcium sodium silicate (Andesine)	-	-	-	$(Na,Ca)Al_{1-2}Si_{3-2}O_8$	268.60	-	-	-
Sodium potassium aluminium silicate	Sodium potassium aluminium silicate	66402-68-4 /12736-96-8	Silicic acid, aluminium potassium sodium salt	$(Na,K)AlSi_3O_8$	301.34	-	insoluble	white powder
Sodium silver aluminium silicate	Sodium silver aluminium silicate	-	-	-	-	-	insoluble	white powder
Aluminium Calcium Sodium Silicate	Aluminium Calcium Sodium Silicate	1344-01-0	Silicic acid, aluminium calcium sodium salt	$AlCaNaO_4Si^{+2}$	182.13	-	73 mg/l	white powder
Magnesium aluminium silicate (Argila)	Magnesium aluminium silicate	1327-43-1	Silicic acid, aluminium magnesium salt	$AlMgO_4Si^+$	143.37	0.650	2.24 mg/L	white powder
Aluminium Magnesium Silicate	Magnesium aluminium silicate	1327-43-1	Silicic acid, aluminium magnesium salt	$AlMgO_4Si^+$	143.37	0.650	2.24 mg/L	white powder
Alumina Magnesium	-	50958-44-6	aluminium	$AlMgO_4Si^+$	143.37	-	-	-

Metasilicate			magnesium tetraoxidosilane					
Potassium Aluminium Silicate (Moonstone Powder)	Mica	12001-26-2	Potassium aluminium silicate; Mica; Muscovite	$KAl_2[AlSi_3O_{10}](OH)_2$	398.31	-	-	white powder
Ammonium Silver Zinc Aluminium Silicate	Ammonium Silver Zinc Aluminium Silicate	-	-	$Ag_2Al_2H_8N_2O_21Si_7Zn_2$	969.14	-	-	-
Pumice (volcanic glass)	Pumice	1332-09-8	Amorphous aluminium silicate	-	-	-	-	-
Loess (aeolian/wind-blown silt)	Loess	-	-	-	-	-	-	-
Calcium aluminium borosilicate (Al2O3, 14.5%)	Calcium aluminium borosilicate	65997-17-3	-	-	-	-	Insoluble	white solid
Talc (Magnesium Silicate, containing a small portion of aluminium silicate)	Talc	14807-96-6	Talc ($Mg_3H_2(SiO_3)_4$) (CI 77718); Talcum	$Mg_3(Si_4O_{10})(OH)_2$	379.27	-	Insoluble	-
Mica (CI 77891; silicate minerals of varying chemical composition)	CI 77891	13463-67-7	Titanium dioxide	TiO_2	79.87	-	Insoluble	white solid
Carbohydrates								
Aluminium starch octenylsuccinate (E1452)	Aluminium starch octenylsuccinate	9087-61-0	Starch, hydrogen 2-(octen-1-yl)butanedioate, aluminium salt	$C_{21}H_{44}O_3$	344.57		poorly soluble in water	white powder
Aluminium Sucrose Octasulfate	Aluminium Sucrose Octasulfate	54182-58-0	Aluminium, hexadeca-mu-hydroxytetracosahydroxy[mu8-[1,3,4,6-tetra-O-sulfo-beta-D-fructofuranosyl] alfa-D-gluycopyranoside tetrakis(hydrogen sulfato)(8-)]] hexadeca-	$R-(CH_2OSO_3^-)_8$ $[Al_2(OH)_5^+]_8$ R = sucrose $C_{12}H_{54}Al_{16}O_{75}S_8$	2086.74		insoluble	white powder
Fatty acids salts								
Aluminium dimyristate	Aluminium dimyristate	56639-51-1	Hydroxybis(myristato-O)aluminium	$2[C_{14}H_{28}O_2]Al.HO$	498.71	-	slightly soluble in water	white powder
Aluminium distearate	Aluminium distearate	300-92-5	Stearic acid aluminium salt	$C_{36}H_{71}AlO_5$	610.93	-	insoluble	white powder
Aluminium stearate	Aluminium stearate	7047-84-9	Aluminium hydroxide	$C_{18}H_{37}AlO_4$	344.47	8.216 7.97	0.00272 mg/L @	white powder

			stearate; aluminium monostearate; Dihydroxyaluminium stearate				25 °C (est)	
Aluminium tristearate	Aluminium tristearate	637-12-7	Stearic acid, aluminium salt	$C_{54}H_{105}AlO_6$	877.39	-	insoluble	white powder
Aluminium octadecanoate	Aluminium tristearate	637-12-7	aluminium(3+) ion trioctadecanoate	$C_{54}H_{105}AlO_6$	877.39	10.81 7.15	1.02e-05 mg/mL	white powder
Hydroxyaluminium Distearate	Aluminium distearate	300-92-5	-	$C_{36}H_{71}AlO_5$	610.93	-	insoluble	white powder
Aluminium magnesium hydroxystearate	-	-	Aluminium magnesium 18-hydroxyoctadecanoate	$C_{36}H_{70}AlMgO_6^{+3}$	649.65	-	-	-
Aluminium stearoyl glutamate	Aluminium stearoyl glutamate	-	Aluminium 2-(1-oxooctadecylamino)pentanedioate (1:3)	$C_{23}H_{43}AlNO_5$	426.21	-	slightly soluble in water	solid

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