Australian Government
Department of Health and Aged Care
Australian Industrial Chemicals Introduction Scheme

Use of Aluminium in Antiperspirants

Evaluation statement

22 December 2022

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Use of aluminium in antiperspirants

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Reason for the evaluation

Evaluation is needed to provide information on human health risks.

Parameters of evaluation

These chemicals are listed on the Australian Inventory of Industrial Chemicals (the Inventory). This evaluation is a human health risk assessment for use of the chemicals in antiperspirants and deodorants.

These chemicals were previously assessed under the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework, under the National Industrial Chemicals Introduction and Assessment Scheme (NICNAS). The IMAP reports recommended further investigation of these chemicals to estimate aluminium exposures from antiperspirants and deodorants and to determine whether these exposures significantly contribute to total systemic exposure to aluminium (NICNAS 2014a; NICNAS 2014b; NICNAS 2014c). There has also been ongoing public concern (including in the media) that the use of aluminium in antiperspirants may be a significant source of exposure, potentially leading to health issues such as breast cancer and Alzheimer's disease. However, the most recent data indicated that a causal relationship could not be established between breast cancer and exposure to aluminium (RIVM 2020). According to the Dutch National Institute for Public Health and the Environment (RIVM), 'there is little evidence that aluminium can be associated with Alzheimer's disease in the general population' (RIVM 2020).

In 2013, the Norwegian Scientific Committee for Food Safety (VKM) reported that antiperspirants contributed significantly to the total systemic aluminium exposure compared to diet, at least for the Norwegian population that was used in the study (VKM 2013). But in 2020, the Dutch National Institute for Public Health and the Environment (RIVM) concluded that 'the contribution of personal care products to the aggregate exposure is relatively small. This is particularly true of dermally applied products, given that only a very small fraction of aluminium is absorbed via the skin.' Additional information has since become available, including new experimental data on human dermal absorption (SCCS 2020) and exposure data (SCCS 2022).

The evaluation covers the risks to the public only, as risks to workers were previously assessed under the IMAP framework. This evaluation report should be read in conjunction with the relevant IMAP assessments for aluminium salts:

- Aluminium zirconium chloride hydroxides: Human health tier II assessment (NICNAS 2014a)
- Aluminium chlorides: Human health tier II assessment (NICNAS 2014b)
- Aluminium sulfates: Human health tier II assessment (single and double salts) (NICNAS 2014c).

Summary of evaluation

Summary of introduction, use and end use

Aluminium salts are used in a wide range of cosmetic and non-cosmetic products, which have been assessed previously in IMAP assessment reports (NICNAS 2014a; NICNAS 2014b; NICNAS 2014c).

This evaluation will focus solely on the use of aluminum salts in antiperspirants. The term 'antiperspirant' used in this evaluation refers to the following products:

- antiperspirant products, which aim to reduce the amount of sweat produced by the body (EC CosIng)
- deodorant products, which aim to reduce or neutralise unpleasant body odour (EC CosIng).

In addition, some aluminium salts, including potassium alum (CAS No. 7784-24-9 and CAS No. 10043-67-1) and sulfuric acid, aluminium salt (3:2), octadecahydrate (CAS No. 7784-31-8) have astringent properties (ability to tighten the skin pores), often used in combination with

antiperspirant formulations. Therefore, they will be considered as having potential use in antiperspirants.

The Scientific Committee on Consumer Safety (SCCS) reported concentrations of aluminium chlorohydrate in antiperspirants which were: 38, 14.5 and 21% (equivalent to 9.5, 3.6 and 5.2% Al) in aerosol, roll-on and stick formulations, respectively (SCCS 2014). Based on data from a 2016 industry survey the total aluminium concentration in a range of deodorant and antiperspirant products was 3.24–7.7%.

Human health

Summary of health hazards

The toxicological profile of these aluminium salts has been established in previous assessments (NICNAS 2014a; NICNAS 2014b; NICNAS 2014c). A summary is provided below. For the purpose of this evaluation, only new information covering human dermal absorption has been included in the **Supporting information** section.

The critical health effects for risk characterisation include systemic long-term effects (developmental toxicity, neurotoxicity), based on studies on aluminium citrate. They also include local acute effects on skin and/or eyes for some of the aluminium salts in the group.

Bioavailability of aluminium salts of chloride, sulfate and hydroxide is considered much lower than that of aluminium citrate (SCCS 2014).

Aluminium is poorly absorbed via the gastrointestinal tract (GIT); however, the SCCS previously indicated that bioavailability would be highly dependent on the aluminium form, with potential 10-fold variations of oral absorption (SCCS 2014). Overall, the oral bioavailability of aluminium is estimated to be 0.3% via drinking water and 0.1% via food (SCCS 2022).

A dermal bioavailability of 0.00052% was estimated in a recent study on dermal absorption (SCCS 2020). Combined with the aluminium found in the faeces in the same study (0.0014%), the overall percentage of bioavailable aluminium was 0.00192%. The study showed that when applied to the skin, 95% of the dose of aluminium contained in antiperspirants and deodorants remained on the skin and did not penetrate the body.

A study in rabbits showed that inhaled aluminium in the olfactory tract could cross the nasal epithelium to reach the brain directly through axonal transport (NICNAS 2014a). Overall, the inhalation intake of aluminium is considered to be low. A conservative value for aluminium uptake by the lung of 3% was considered appropriate for risk assessment (SCCS 2020; SCCS 2022).

Based on the available data, aluminium salts have low acute toxicity via the oral, dermal and inhalation routes.

Local effects have been reported for some aluminium salts. Aluminium chloride ($AlCl_3$) is corrosive to the skin and eyes. Aluminium chloride, hexahydrate (CAS No. 7784-13-6), sulfuric acid, aluminium salt (3:2), octadecahydrate (CAS No. 7784-24-9) and sulfuric acid, aluminium salt (3:2) (CAS No. 10043-01-3) are eye irritants, based on animal studies (NICNAS 2014a; NICNAS 2014c).

Aluminium salts are not considered to be skin sensitisers. The available data on various forms of aluminium salts showed no skin sensitisation reactions in animal studies (NICNAS 2014a; NICNAS 2014b; NICNAS 2014c). Although occasional reactions may occur, dermal sensitivity to aluminium is considered rare (ATSDR 2008; NICNAS 2014a).

Aluminium salts are not considered to be mutagenic. Negative results were observed in bacterial and mammalian cell systems in vitro (SCCS 2014). However, DNA damage was reported at high exposure levels in both in vitro and in vivo tests (SCCS 2014). The SCCS indicated that there could be an indirect genotoxic mode of action for aluminium ion, via induction of oxidative stress. The latest SCCS Opinion (2022) considered there was no genotoxic effects to expect at the levels of aluminium used in cosmetic products.

Aluminium is not considered to be carcinogenic, although the available data are limited for aluminium salts. The SCCS considers that there is no carcinogenic effect to be expected at the levels of aluminium used in cosmetic products (SCCS 2022).

Based on the available data, developmental toxicity was observed with aluminium chloride in pregnant rats, but it was unclear whether the findings were secondary to maternal toxicity (SCCS 2014).

An NOAEL (no observed adverse effect level) of 30 mg/kg bw/day for systemic toxicity of aluminium citrate was determined in a neurodevelopmental toxicity study based on dose-related effects on hindlimb and forelimb grip strength in both male and female pups (Poirier et al., 2011). The NOAEL can be regarded as a worst case for all aluminium salts because aluminium citrate is considered the most bioavailable of the Al salts. This NOAEL was used as reference value in the risk assessment of aluminium salts (SCCS 2014; SCCS 2020; SCCS 2022).

Hazard classifications relevant for worker health and safety

Four of the chemicals in this evaluation satisfy the criteria for classification according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (UNECE 2019) for hazard classes relevant for worker health and safety as follows. This does not consider classification of physical and environmental hazards.

The skin corrosion classification applies only to aluminium chloride (AlCl3) (CAS 7446-70-0).

The eye irritation classifications apply to:

- aluminium chloride, hexahydrate (CAS No. 7784-13-6)
- sulfuric acid, aluminium salt (3:2), octadecahydrate (CAS No. 7784-24-9)
- sulfuric acid, aluminium salt (3:2) (CAS No. 10043-01-3).

These are the existing classifications on the Hazardous Chemicals Information System (HCIS) (Safe Work Australia).

Health hazards	Hazard category	Hazard statement
Skin corrosion/irritation	Skin corr. 1	H314: Causes severe skin burns and eye damage
Serious eye damage/eye irritation	Eye irrit. 2A	H319: Causes serious eye irritation

Summary of health risk

Public

Based on the available use information, the public may be exposed to these chemicals:

- at concentrations up to 38%
- by direct application of these chemicals to the skin, hair, or lips
- by inhaling aerosols.

Although there is widespread exposure to the aluminium salts when used in deodorants and antiperspirants, the available data show that aluminium is not readily absorbed through the skin or via inhalation. Recent studies on dermal absorption have shown that a cosmetic formulation containing 25% aluminium chlorohydrate had an absorption level of 0.0019% through the skin, when taking into account the recovery in urine and faeces (SCCS 2020).

A systemic exposure of 180 µg Al/kg bw/day was calculated for consumer exposure assessment (SCCS 2020). This is compared with a NOAEL of 30 mg/kg bw/day from the neurodevelopmental toxicity study in rats.

Based on the calculated systemic exposure doses (SED) (see **Human exposure section**), the following margin of safety (MOS) values for exposure from antiperspirants were determined:

- For dermal exposure:
  - MOS = 6792 for non-spray formulations
  - MOS = 8823 for spray formulations.
- For inhalation exposure:
  - MOS = 23047 for respirable particles in deep lung
  - MOS = 76923 for respirable particles deposited in upper respiratory tract
  - MOS = 416667 for non-respirable particles.

In the latest SCCS Opinion (2022), a more conservative value of the MOS for inhalation was estimated, assuming that 100% of the sprayed product is available for inhalation (SCCS 2022):

- MOS = 703.

Therefore, based on the calculated MOS values, the contribution of antiperspirants to overall aluminium exposure is low, and a link between antiperspirants and potential health issues is considered extremely unlikely. In conclusion, there are no identified risks to the public that require management.

Conclusions

The conclusions of this evaluation are based on the information described in this statement.

The Executive Director is satisfied that the identified human health risks can be managed within existing risk management frameworks. This is provided that all requirements are met under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory.

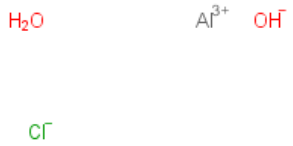
Note: Obligations to report additional information about hazards under *Section 100 of the Industrial Chemicals Act 2019* apply.

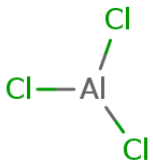
Supporting information

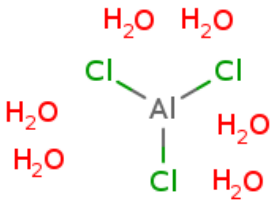
Grouping rationale

Aluminium salts were previously assessed under the IMAP for human health. They were recommended for further investigation, with a focus on antiperspirants. While aluminium is used in various cosmetic products, its use is mostly under an insoluble form and unlikely to be absorbed through the skin. However, aluminium compounds in antiperspirants are water-soluble and may present a higher degree of absorption through the skin, before forming insoluble complexes with sweat. Therefore, this evaluation will focus on the aluminium salts with reported use in antiperspirants. This includes salts having reported use as antiperspirant, deodorant and/or astringent, as these are typical antiperspirant components. From the previous IMAP assessments, all but 3 chemicals have been included in this evaluation. The risk resulting from the use of aluminium in antiperspirants is considered to be representative of the risk resulting from the use in other types of cosmetic products.

Chemical identity

Chemical name	Aluminium chloride, basic
CAS No.	1327-41-9
Synonyms	aluminum chlorohydrate (INCI)
	aluminium chlorhydroxide
	aluminium hydroxide chloride
	aluminium chloride hydroxide oxide, basic
	aluminium chloride oxide
	aluminium chlorohydrol
	aluminium sesquichlorohydrate
Structural formula	
Molecular formula	$AlClH_2O$
Molecular weight (g/mol)	97.45
SMILES	O.[OH-].[Al+3].[Cl-]

Chemical name	Aluminium chloride (AlCl3)
CAS No.	7446-70-0
Synonyms	aluminum chloride (INCI)
	aluminium chloride anhydrous
	aluminium trichloride
Structural formula	
Molecular formula	$AlCl_3$
Molecular weight (g/mol)	133.341
SMILES	Cl[Al](Cl)Cl

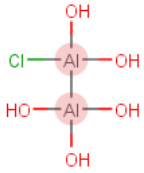
Chemical name	Aluminium chloride, hexahydrate
CAS No.	7784-13-6
Synonyms	aluminum chloride (INCI)
	aluminium trichloride hexahydrate
	aluminium(III) chloride, hexahydrate
Structural formula	
Molecular formula	$AlCl_3.(H_2O)_6$ or $AlCl_3H_{12}O_6$
Molecular weight (g/mol)	241.43
SMILES	O.O.O.O.O.O.Cl[Al](Cl)Cl

Chemical name	Aluminium chloride hydroxide

CAS No.	10284-64-7
Synonyms	aluminium chloride dihydroxide
	aluminum dichlorohydrate (INCI)
	basic aluminium chloride
	chlorodihydroxyaluminium
	dichlorotetrahydroxydialuminium
Structural formula	No structural diagram available
Molecular formula	$Al_2Cl_3H_3O_3$
Molecular weight (g/mol)	211.344
SMILES	[OH-].[OH-].[OH-].[Al+3].[Al+3].[Cl-].[Cl-].[Cl-]

Chemical name	Aluminium chloride hydroxide (Al4Cl3(OH)9)
CAS No.	11089-92-2
Synonyms	tetraaluminium trichloride nonahydroxide
	aluminum sesquichlorohydrate (INCI)
Structural formula	No structural diagram available
Molecular formula	$Al_4Cl_3H_9O_9$
Molecular weight (g/mol)	367.35
SMILES	[OH-].[OH-].[OH-].[OH-].[OH-].[OH-].[OH-].[OH-].[OH-].[Al+3].[Al+3].[Al+3].[Al+3].[Cl-].[Cl-].[Cl-]

Chemical name	Aluminium chloride hydroxide (Al2Cl(OH)5)
CAS No.	12042-91-0
Synonyms	aluminium chlorhydrol
	aluminium chlorohydrate
	aluminum chlorohydrate (INCI)
	aluminium hydroxide chloride

Structural formula	
Molecular formula	$Al_2ClH_5O_5$
Molecular weight (g/mol)	174.452
SMILES	O[Al](O)(O)[Al](O)(O)Cl

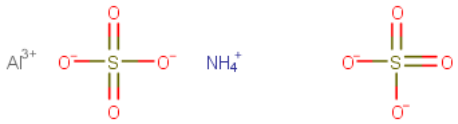
Chemical name	Aluminium zirconium chloride hydroxide
CAS No.	57158-29-9
Synonyms	aluminum zirconium chlorhydrate
Structural formula	No structural diagram available
Molecular formula	$Al_2Cl_7H_7O_7Zr_2$
Molecular weight (g/mol)	603.631
SMILES	[OH-].[OH-].[OH-].[OH-].[OH-].[OH-].[OH-].[Al+3].[Al+3].[Cl-].[Cl-].[Cl-].[Cl-].[Cl-].[Cl-].[Cl-].[Zr+4].[Zr+4]

Chemical name	Aluminium zirconium chloride hydroxide (Al4ZrCl4(OH)12)
CAS No.	98106-52-6
Synonyms	aluminum zirconium tetrachlorohydrate (INCI)
Structural formula	tetraaluminium zirconium tetrachloride dodecahydroxide No structural diagram available
Molecular formula	$Al_4Cl_4H_{12}O_{12}Zr$
Molecular weight (g/mol)	545.04
SMILES	[OH-].[OH-].[OH-].[OH-].[OH-].[OH-].[OH-].[OH-].[OH-].[OH-].[OH-].[OH-].[Al+3].[Al+3].[Al+3].[Al+3].[Cl-].[Cl-].[Cl-].[Cl-].[Zr+4]

Chemical name	Aluminium zirconium chloride hydroxide (Al8ZrCl5(OH)23)
CAS No.	98106-54-8
Synonyms	octaaluminium zirconium pentachloride tricosahydroxide
Structural formula	No structural diagram available
Molecular formula	$Al_8Cl_5H_{23}O_{23}Zr$
Molecular weight (g/mol)	875.5
SMILES	[OH-].[Al+3].[Al+3].[Al+3].[Al+3].[Al+3].[Al+3].[Al+3].[Al+3].[Cl-].[Cl-].[Cl-].[Cl-].[Cl-].[Zr+4]

Chemical name	Sulfuric acid, aluminium potassium salt (2:1:1), dodecahydrate
CAS No.	7784-24-9
Synonyms	potassium alum (INCI) alum potash potassium alum, dodecahydrate aluminium potassium disulfate dodecahydrate aluminium potassium sulfate
Structural formula	No structural diagram available
Molecular formula	$KAl(SO_4)_2.(H_2O)_{12}$ or $AlH_{24}KO_{20}S_2$
Molecular weight (g/mol)	474.382
SMILES	O.O.O.O.O.O.O.O.O.O.O.O.[O-]S(=O)(=O)[O-].[O-]S(=O)(=O)[O-].[Al+3].[K+]

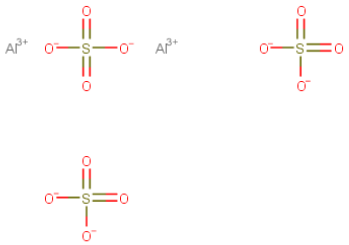
Chemical name	Sulfuric acid, aluminium ammonium salt (2:1:1)
CAS No.	7784-25-0
Synonyms	ammonium aluminium sulfate aluminum ammonium sulfate (3:1:3)

	aluminum sulfate ammonium salt
Structural formula	ammonium alum (INCI) 
Molecular formula	$AlNH_4(SO_4)_2$ or $AlH_4NO_8S_2$
Molecular weight (g/mol)	237.15
SMILES	[NH4+].[O-]S(=O)(=O)[O-].[O-]S(=O)(=O)[O-].[Al+3]

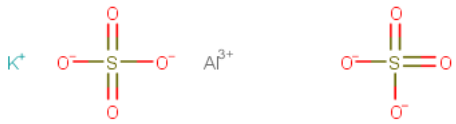
Chemical name	Sulfuric acid, aluminium ammonium salt (2:1:1), dodecahydrate
CAS No.	7784-26-1
Synonyms	alum, ammonium
	aluminium ammonium bis(sulfate) dodecahydrate
	aluminium ammonium disulfate dodecahydrate
	aluminium ammonium sulfate (1:1:2) dodecahydrate
	aluminium ammonium sulfate
Structural formula	No structural diagram available
Molecular formula	$AlNH_4(SO_4)_2.(H_2O)_{12}$ or $AlH_{28}NO_{20}S_2$
Molecular weight (g/mol)	453.32
SMILES	[NH4+].O.O.O.O.O.O.O.O.O.O.O.O.[O-]S(=O)(=O)[O-].[O-]S(=O)(=O)[O-].[Al+3]

Chemical name	Sulfuric acid, aluminium salt (3:2), octadecahydrate
CAS No.	7784-31-8
Synonyms	aluminium sulfate octadecahydrate
	cake alum octadecahydrate
	dialuminium sulfate octadecahydrate
Structural formula	No structural diagram available

Molecular formula	$Al_2(SO_4)_3.(H_2O)_{18}$ or $Al_2H_{36}O_{30}S_3$
Molecular weight (g/mol)	666.41
SMILES	O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.O.[O-]S(=O)(=O)[O-].[O-]S(=O)(=O)[O-].[O-]S(=O)(=O)[O-].[Al+3].[Al+3]

Chemical name	Sulfuric acid, aluminium salt (3:2)
CAS No.	10043-01-3
Synonyms	aluminium alum dialuminium trisulfate aluminium sesquisulfate aluminum sulfate (INCI)
Structural formula	
Molecular formula	$Al_2(SO_4)_3$ or $Al_2O_{12}S_3$
Molecular weight (g/mol)	342.15
SMILES	[O-]S(=O)(=O)[O-].[O-]S(=O)(=O)[O-].[O-]S(=O)(=O)[O-].[Al+3].[Al+3]

Chemical name	Sulfuric acid, aluminium potassium salt (2:1:1)
CAS No.	10043-67-1
Synonyms	aluminium potassium disulfate aluminium potassium sulfate aluminium potassium sulfate, anhydrous potassium alum (INCI)

Structural formula	
Molecular formula	$KAl(SO_4)_2$ or $AlKO_8S_2$
Molecular weight (g/mol)	258.21
SMILES	[O-]S(=O)(=O)[O-].[O-]S(=O)(=O)[O-].[Al+3].[K+]

Relevant physical and chemical properties

Aluminium salts used in antiperspirants are usually water-soluble salts of aluminium and/or zirconium, able to form insoluble gels on contact with the skin. The chemicals in this evaluation have relatively high molecular weight, low partition coefficient (log K_{ow}) and high positive charges, limiting dermal absorption (CAS SciFinder; Chemwatch; NCBI; SCCS 2020).

Introduction and use

Australia

Under previous calls for information, aluminium chloride, basic (CAS No. 1327-41-9) was reported to be used as an odour agent and in other (unspecified) uses. Aluminium chloride ($AlCl_3$) (CAS No. 7446-70-0) was reported to be used in fillers and process regulators. The total volume for both chemicals introduced into Australia, reported under previous mandatory and/or voluntary calls for information, was between 1000 and 9999 tons (NICNAS 2014).

No other specific Australian use, import, or manufacturing information has been identified for the chemicals in this evaluation.

International

All the chemicals in this evaluation have reported cosmetic use in deodorants and antiperspirant products (Chemwatch; CIR, 2013; DeLima Associates; EC CosIng; NCBI; NLM).

Most of the chemicals are known ingredients for antiperspirants, deodorants and astringents (EC CosIng). In the Consumer Product Information Database (CPID), the maximum concentrations reported for use in antiperspirants were 20.7% for aluminium chloride basic (CAS No. 1327-41-9) and 20% for aluminium zirconium chloride hydroxide (CAS No. 57158-29-9) (DeLima Associates). In France, the maximum concentration of aluminium salts (based on aluminium chlorohydrate, CAS No. 1327-41-9) used in deodorants and AP was reported to be 20% (equivalent to 5% Al) (AFSSAPS 2011). The SCCS reported similar range of concentrations of aluminium chlorohydrate used in deodorants and antiperspirants (SCCS 2014):

- 38% in aerosol formulations (equivalent to 9.5% of Al)
- 14.5% in roll-on formulations (equivalent to 3.61% Al)
- 21% in stick formulations (equivalent to 5.2% Al).

The following concentrations in cosmetics were identified in an industry survey (SCCS 2022). Six companies provided comprehensive data on Al use across a range of cosmetic products for the year 2016:

Table 1. Concentrations of various aluminium salts in cosmetic products (SCCS 2022)

CAS No	Chemical Name	Max conc. %	Mean conc. %
10043-01-3	Sulfuric acid, aluminium salt (3:2)	6.25	5.1
12042-91-0	Aluminium chloride hydroxide (Al2Cl(OH)5)	25.5	18.5
1327-41-9	Aluminium chloride, basic	30.9	21.3
57158-29-9	Aluminium zirconium chloride hydroxide	10.2	10.2
7446-70-0	Aluminium chloride (AlCl3)	12	11.1
7784-13-6	Aluminium chloride, hexahydrate	12	11.1
7784-24-9	Sulfuric acid, aluminium potassium salt (2:1:1), dodecahydrate	6.25	5.1

By combining % Al in the ingredient with % of Al-ingredient used in the product, the following concentration values for Al in each product category were determined:

Table 2. Concentrations of aluminium in deodorants and antiperspirants (SCCS 2022)

Product type	Max aluminium conc %	Mean aluminium conc %
Deo roll on – gel	6.18	1.7
Deo roll on – roll on	5.63	1.45
Deo roll on – stick	7.73	1.05
Deo spray – Anti perspirant	3.24	0.32
Deo spray – Pump	4.88	1.17

Existing Australian regulatory controls

Public

Currently there are no regulatory controls in place for the use of these aluminium salts in cosmetic products.

Workers

Aluminium chloride ($AlCl_3$) (CAS 7446-70-0) is classified in the HCIS (Safe Work Australia) as follows:

- CAS 7446-70-0: Skin corr. 1 (H314: Causes severe skin burns and eye damage).

Aluminium chloride, hexahydrate (CAS No. 7784-13-6), sulfuric acid, aluminium salt (3:2), octadecahydrate (CAS No. 7784-24-9) and sulfuric acid, aluminium salt (3:2) (CAS No. 10043-01-3) are classified in the HCIS as follows:

- CAS No. 7784-13-6: Eye irrit. Cat 2A (H319: Causes serious eye irritation).

None of the remaining aluminium salts in this evaluation are classified in the HCIS.

International regulatory status

Canada

Aluminium zirconium complexes are currently listed on the 'Canada Cosmetic Ingredient Hotlist - List of ingredients that are restricted for use in cosmetic products' and are not permitted in deodorants and in antiperspirant aerosol dispensers (Chemwatch).

European Union

Aluminium zirconium chloride hydroxide (CAS No. 98106-52-6) and aluminium zirconium chloride hydroxide (CAS No. 98106-54-8) are listed on the 'EU Cosmetics Regulation 1223/2009 Annex III—List of substances which cosmetic products must not contain except subject to the restrictions laid down'. They are currently restricted at a maximum concentration of 20% (as anhydrous aluminium zirconium chloride hydroxide) and 5.4% (as zirconium) in antiperspirants (EC CosIng).

In addition, the following conditions apply:

- The ratio of the number of aluminium atoms to that of zirconium atoms must be between 2 and 10
- The ratio of the number of (Al+Zr) atoms to that of chlorine atoms must be between 0.9 and 2.1
- Not to be used in aerosol dispensers (sprays)
- Do not apply to irritated or damaged skin.

Aluminium chloride, basic (CAS No. 1327-41-9), aluminium chloride and aluminium sulfate are listed on the EU Community Rolling Action Plan (CORAP) list.

Asia

Aluminium zirconium chloride hydroxide (CAS No. 98106-52-6) and aluminium zirconium chloride hydroxide (CAS No. 98106-54-8) are listed on the 'Philippines List of substances which cosmetics products must not contain except subject to the restrictions and conditions specified' (Chemwatch). Restrictions are the same as in the European Union.

Human exposure

Public

Based on the available information, the most prominent use of aluminium salts in cosmetic products is in deodorants and antiperspirants (SCCS 2020). Depending on the formulation

and product type, the public may be exposed to the chemicals via dermal and inhalation routes.

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 K_{ow} and positive charge limit the potential for skin penetration through the stratum corneum. Absorption across the skin is further minimised by the formation of protein complexes in the outermost layers of the stratum corneum. These chemical properties limit the systemic delivery of aluminium via skin. Other cosmetic products, such as lipsticks and toothpastes, contain mainly insoluble forms of aluminium (SCCS 2022).

Health hazard information

Toxicokinetics

Dermal absorption

In a human dermal absorption study, 6 female subjects were exposed to 1.5 g of an antiperspirant formulation containing 25% of aluminium chlorohydrate with radiolabelled aluminium ^{26}Al. On each axilla, an amount of 0.75 g of antiperspirant was applied under protective gauze. Measurements (blood, urine, faeces, tape stripping and skin biopsies) were collected in the first 24 hours and the following ten days. At the end the treatment, the subjects were given an intravenous (IV) dose of 1 µg/mL radiolabelled aluminium. Radioactivity in blood and urine was monitored for 24 hours. The majority (more than 95%) of the applied topical dose was found on clothing, experimental equipment or washed off the skin (SCCS 2020).

In another cohort, 6 female subjects were exposed to the same dermal exposure protocol as above. Within the first 24 hours, tape stripping was performed at 4 different sites on the axilla, at 20 min, 1 h, 4 h and 24 h post application. Skin punch biopsy was performed 24 h post application. The overall recovery of the applied dose was 69% (mostly in skin wash). Aluminium in the bloodstream was below detection limits. A total of 0.0003% and 0.0014% of the applied dose were recovered in the urine and faeces, respectively. A total of 70% of the IV dose was excreted in urine. Based on these results, a dermal absorption value of 0.00052% was calculated. Combined with the Al found in the faeces in the same study (0.0014%), the overall percentage of bioavailable Al is 0.00192%. (SCCS 2020).

Human health risk characterisation

Critical health effects

The critical health effects include:

- Systemic long-term effects due to neurotoxicity and developmental toxicity observed in animal.

With a NOAEL of 30 mg/kg bw/day from the neurodevelopmental toxicity study in rats, a systemic exposure at the NOAEL was calculated to be 180 µg Al /kg bw/day. This was selected as the point of departure for the risk assessment (SCCS 2020).

Public risk

Systemic Exposure Dose (SED) calculations

Although there is widespread exposure to the aluminium salts when used in deodorants and antiperspirants, the available data show that aluminium is not readily absorbed through the skin or via inhalation. Once in contact with skin, the mode of action of these salts is to form insoluble complexes to neutralise sweat. Recent studies on dermal absorption have shown that a cosmetic formulation containing 25% aluminium chlorohydrate gave an absorption level of 0.00052% through the skin, based on urinary excretion. When considering the amount of aluminium recovered in urine and faeces, the absorption rate was estimated to be 0.00192% (see **Dermal absorption** section)

Absorption via inhalation is also expected to be low. For the purpose of modelling SCCS made a conservative estimate of 3% for lung uptake of aluminium.

Dermal exposure

Based on 2 estimated values for dermal absorption rates, the following internal systemic exposure doses (SED) values for Al were calculated as (SCCS 2020):

- Where the dermal bioavailability of aluminium chlorohydrate is 0.00192%:
    - SED = 0.0265 µg Al/kg bw/day for non-spray formulations
    - SED = 0.0204 µg Al/kg bw/day for spray formulations.

- Where the dermal bioavailability of aluminium chlorohydrate is 0.00052%:
    - SED = 0.007 µg Al/kg bw/day for non-spray formulations
    - SED = 0.006 µg Al/kg bw/day for spray formulations.

For non-spray formulations the calculation used a concentration of 6.25% aluminium (from aluminium chlorohydrate) and used the 90th percentile product exposure for non-spray deodorants/antiperspirants. For spray formulations the calculation used a concentration of 10.6% on the non-volatile fraction (based on 2.86% in full formulation) and dermal product exposure of 10 mg product/kg bw/day.

Inhalation exposure

The following internal SED values for Al were estimated based on an experimental measure of lung exposure from antiperspirants (SCCS 2020):

- SED = 0.00781 µg/kg bw/day for respirable particles in deep lung
- SED = 0.00234 µg/kg bw/day for respirable particles deposited in upper respiratory tract
- SED = 0.000432 µg/kg bw/day for non-respirable particles.

However, in the latest SCCS Opinion (2022), the total systemically available dose or SED of aluminium in an antiperspirant spray was estimated to be 0.256 µg/kg bw/day, via inhalation only (SCCS 2022). This value was estimated with the conservative assumptions that lung

uptake is 3% and that 100% of the particles released from a spray may be inhaled by the user.

Margin of Safety (MOS) calculations

Risk from dermal exposure

Based on the calculated SED, the following margin of safety (MOS) values were determined (SCCS 2020):

- Where the dermal bioavailability of aluminium compounds is 0.00192%:
    - MOS = 6792 for non-spray formulations
    - MOS = 8823 for spray formulations.

- Where the dermal bioavailability of aluminium compounds is 0.00052%:
    - MOS = 25714 for non-spray formulations
    - MOS = 30000 for spray formulations.

Risk from inhalation exposure

Based on the calculated SED, the following MOS were calculated (SCCS 2020):

- MOS = 23047 for respirable particles in deep lung
- MOS = 76923 for respirable particles deposited in upper respiratory tract
- MOS = 416667 for non-respirable particles.

Using the calculated SED in the 2022 SCCS opinion of 0.256 µg/kg bw/day, an MOS of 703 was determined, for inhalation from antiperspirant sprays only (excluding other types of aerosols and spray products).

Conclusion

The latest SCCS Opinion (2022) covered a range of cosmetic products containing aluminium, beyond the scope of this evaluation. It showed that antiperspirants were safe for use at the maximum levels provided to them by industry (see Table 2).

The SCCS noted that food may contribute to the aggregate exposure to aluminium in a similar order of magnitude as cosmetics, while the RIVM considered that food was the major source of exposure to aluminium (RIVM 2020). Pharmaceuticals such as antacids may contribute to some extent but are consumed by only a small fraction of the population (SCCS 2022). Given the low contribution of antiperspirants to overall exposure to aluminium, the risk to the public from using aluminium in antiperspirants is considered to be low.

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