# Cosmetics Industry Remains Confident: Exposure to Aluminium from Cosmetic Products is Negligible

## BfR Symposium – 26 & 27 November 2014

1. Background on Aluminium and Cosmetics
2. How Antiperspirants Work
3. Existing Skin Absorption Data (SCCS / BfR Opinions)
4. New Study in Progress

**Aluminium Consortium – IKW – Cosmetics Europe**

# Authoritative assessments see no plausible evidence to link consumer exposure to aluminium with Alzheimer's disease or cancer

- Several Decades of Concern and Scientific Scrutiny.
- No evidence of harm at current levels of consumer exposure.
- Recent Authoritative Expert Reviews:

  Opinions on Dietary Exposure

  - **EFSA 2008:** European Food Safety Authority
  - **JECFA 2008 and JECFA 2011:** World Health Organisation

  Opinions on Cosmetic Exposure

  - **BfR 2014** German Federal Institute for Risk Assessment
  - **SCCS 2014:** EU Scientific Committee on Consumer Safety

## Why is ill health implausible?

- Daily Exposure from cosmetics is **very low** (micrograms)
- It is a **minor** contribution to overall consumer exposure

## Why is there still controversy?

- **Skin absorption** is crucial to the risk assessment
- The small exposure from cosmetics is **difficult** to **distinguish** from **other sources** of aluminium exposure
- Need to **strengthen** the **scientific basis** of the skin absorption data

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## Public Health (11-04-2014)

**Scientific Opinion on Aluminium in cosmetic products published today**

Today, the Commission's independent Scientific Committee on Consumer Safety (SCCS) published its Opinion on Aluminium in cosmetics such as lipstick, deodorants and toothpastes.

Aluminium is a known systemic toxicant at high doses. Following reports and concerns raised, the SCCS was requested to assess the possible risk for human health due to the presence of aluminium in cosmetics, in particular in products such as antiperspirants and deodorants, lipstick and toothpastes, considering the exposure from other sources such as food and food supplements.

In case the estimated exposure of aluminium caused concern, the SCCS was further asked to recommend safe concentration limits for the presence of aluminium in cosmetics.

After studying the available literature on exposure to, and health risks from aluminium in cosmetic products, the SCCS expressed several considerations. For example:

- Aluminium in the levels reached with cosmetic use is unlikely to be carcinogenic.
- There is no evidence that using antiperspirants can lead to levels of aluminium that would be harmful to health.
- There is no plausible evidence that the use of aluminium containing cosmetics and skin care products can increase the risk of breast cancer or Alzheimer's disease, Parkinson's disease and other neurodegenerative diseases.

Regarding safe concentration limits, SCCS concluded that there was too little data to draw conclusions, and that internal exposure to aluminium after skin application could be better determined with a human exposure study under real-life conditions.

To read the full Opinion:
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_153.pdf
For more information on the SCCS:
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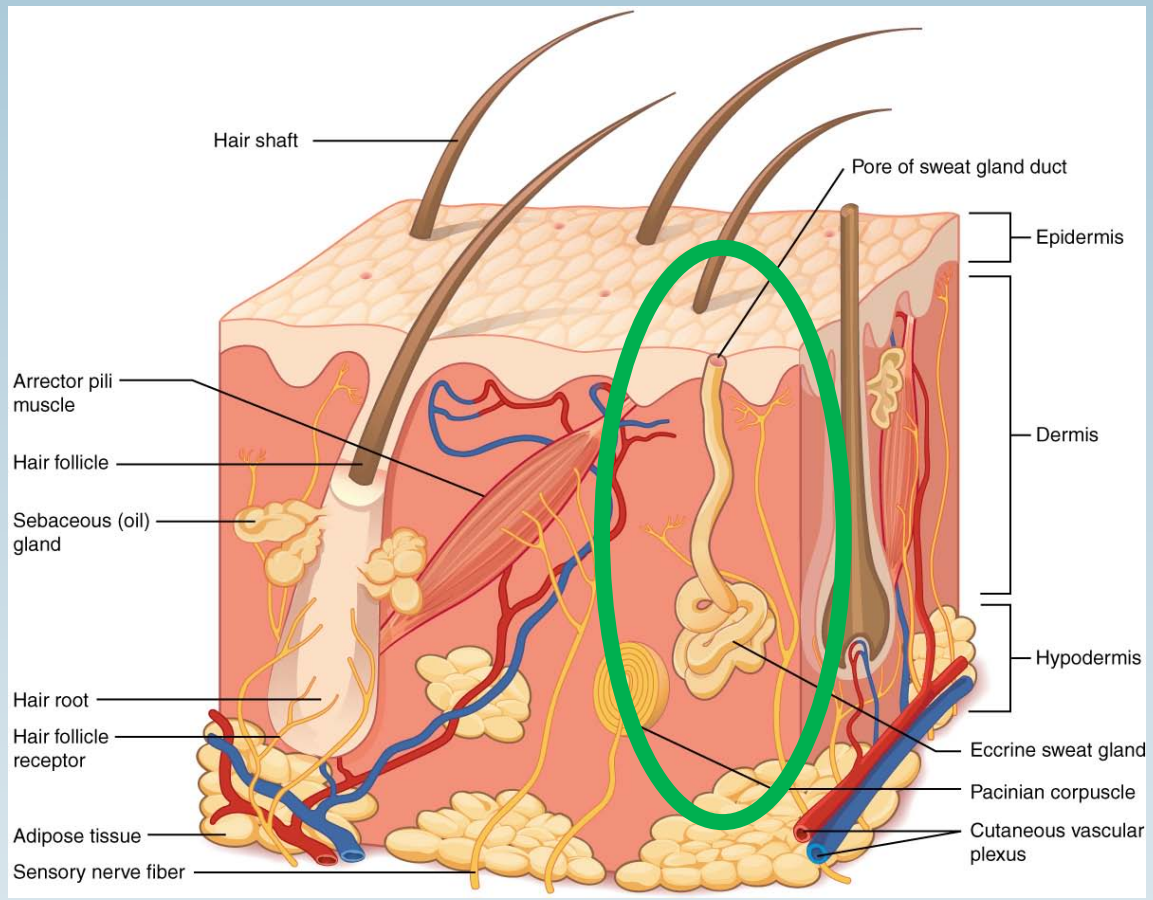
# The contribution from aluminium containing ingredients in cosmetics to consumer exposure is very low

- Aluminium containing ingredients are present in several types of cosmetic products.
- The majority of products use aluminium containing ingredients that are ***insoluble***, which means they are not free to be absorbed across the skin e.g.
  - insoluble **pigments** or naturally occurring **clays** and **minerals** (aluminium is the third most abundant element in the earth's crust).
- Some products (e.g. lipstick and toothpaste) may be ingested in small quantities, but amount is small compared to the diet.
- Antiperspirants are the principal use of ***soluble*** aluminium containing ingredients (aluminium salts) in cosmetics. Therefore, it is important to understand how much is absorbed.

# Skin is a Barrier:
# Protein Complexes Reduce Skin Absorption

Many metal salts form complexes with **proteins***

Formation of **protein complexes** in the stratum corneum **minimises absorption** across the skin **




*Structure of the skin Illustration from Anatomy & Physiology, Connexions. http://cnx.org/content/col11496/1.6/*
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** Strassburger J & Coble DW (1987). J Soc Cosmet Chem 38; **Hostynek JJ (2003). Food Chem Toxicol 41*

# Skin Absorption

# Mode of Action of Antiperspirants Containing Aluminium Salts

# Aluminium salts from antiperspirant form insoluble plugs in the sweat duct *

Soluble aluminium salts **diffuse** into quiescent sweat ducts…

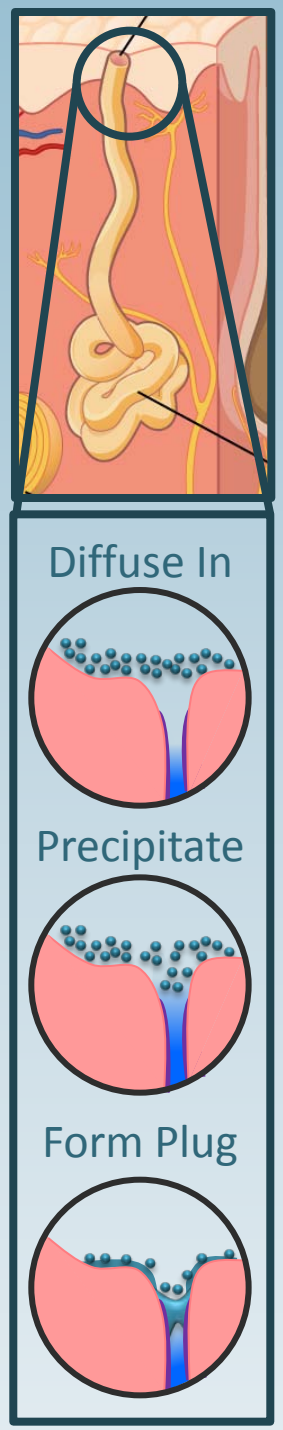
…bicarbonate in sweat **neutralises** aluminium salts so that they **precipitate** as **insoluble polymeric** (high molecular weight) aluminium hydroxide gel plugs…

… and interact with **mucopolysaccharide** duct lining…

… an insoluble **plug** is formed in **the duct**, which prevents sweat from reaching the skin surface until…

…the plugs are **ejected** as upper layers of the skin is worn off.

High molecular weight, insoluble substances cannot penetrate the epidermis and are generally **not bioavailable**. Therefore **precipitated** aluminium hydroxide gel plugs are **unlikely** to be **systemically bioavailable**.






**Strassburger J & Coble DW (1987). J Soc Cosmet Chem 38; Quatrale RP et al (1981). J Soc Cosmet Chem 32*

# Skin Absorption

## Summary of Existing Data

# Flarend (2001): First Human Study Found Very Low Skin Absorption from Radiolabelled Antiperspirant Aluminium Salt *

**Aqueous** aluminium salt antiperspirant (ACH) labelled with rare **$^{26}$Al** radioisotope

**Pilot** study using 2 subjects 

**Single dose**

**Mass balance** attempted, occlusion & tape stripping

**0.012%** of applied dose was absorbed

✓ Good **sensitivity** and **specificity**

✘ **Too few** subjects.

? Would more or less be absorbed during **daily use**?

✘ **Occlusion** (covered skin) often increases absorption.

✘ **Tape stripping** led to severe irritation and broken skin in one subject and mild irritation in the other

✓ Must be interpreted **conservatively**

* Flarend R et al (2001). Food Chem Toxicol 39

# *PMIC (2008): In vitro* Skin Absorption Study*

- A relatively **standard** *in vitro* skin a using *ex vivo* human skin
  - ✓ OECD / GLP / SCCS compliant method
- Assessed absorption of **non-radioactive $^{27}$Al** from 3 antiperspirant products **± tape strip damage**
- Measured the abundant $^{27}$Al stable isotope
  - × **High background** = poor sensitivity
- Large variability in **sample measurement**
  - × **Standard Deviations** were large (63% of mean value)
  - × **Mass Balance** varied from 51±10% to 141±29% (not valid study)
  - × Study not a valid study by **SCCS criteria**
- **No significant increase** in aluminium in the **receptor fluid**.

* Report by PMIC Podesta-Marty International Consultants (2008); Partially published by Pineau et al. (2012). J Inorg Biochem 110

# *PMIC (2008): In Vitro* Skin Absorption Study – Model Limitations

- Given the way that antiperspirants work, *ex vivo* skin is a poor model
  - *Ductal **plugs unlikely** to be formed*
  - ***Active sweat glands** are required for pH neutralisation and precipitation*
  - ***No sweat flow** so fast diffusion down sweat ducts, aided by gravity*
  - *Slow pH neutralisation leaving **soluble salts in duct lumen***
  - *Protective **mucopolysaccharide** duct lining integrity is uncertain*
- Observed residues in the upper layers of the skin are not surprising due to potential **protein binding** of Al-ions and formation of **insoluble precipitates**.
- **No significant increase** in aluminium in the **receptor fluid**.
- Dead skin is a **poor model** for **living** and **sweating** skin for the assessment of skin absorption of an antiperspirant

# Summary of Existing Data on Skin Absorption

- The in vitro study (PMIC) is not a suitable basis for risk assessment due to model limitations
  - **no significant increase** in aluminium in the receptor fluid
- The Flarend clinical study and knowledge about aluminium chemistry help inform the Risk Assessment
- However, BfR and SCCS both conclude that the
  - The available studies are **inadequate**
  - **More robust** skin absorption data is needed to reduce **uncertainty** in the exposure assessment.
- Based on previous attempts, aluminium absorption is **difficult** to assess and requires a **state-of-the-art study**.

# Skin absorption

## New Clinical Study

Currently underway at a respected independent research institute

- ☑ Study Designed
- ☑ Ethics Approval Received
- ☑ Test Material Prepared
- ☑ Volunteers Recruited
- ☑ Clinical Phases in Progress
- ☐ Chemical Analysis
- ☐ Study Report
- ☐ Submission to Authorities

Results will be available in the second half of 2015

# The Study Will..

… show the **amount absorbed** (absolute bioavailability) following skin exposure to a typical antiperspirant formulation,

… show whether **shaving** alters the amount of aluminium absorbed,

… determine absorption in a **daily use** scenario with realistic consumer use,

… use method capable of **detecting** the **very low** levels of aluminium that might be absorbed, and

… allow exposure to aluminium from antiperspirants to be assessed in the **context** of **total** aluminium exposure.

# How is this study better?

Like Flarend, this study:

- Uses small quantities of $^{26}Al$ radioisotope to be confident the antiperspirant was the **source** of exposure… **Good Sensitivity**
  - ✓ Rare in nature ($^{27}Al$ 100% :$^{26}Al$ < 0.000000000001%)
    Very low endogenous background
  - ✓ Accelerator mass spectrometry (AMS)
- Accurately measure very low levels in blood and urine
  - samples taken over hours, days & weeks to estimate total absorbed

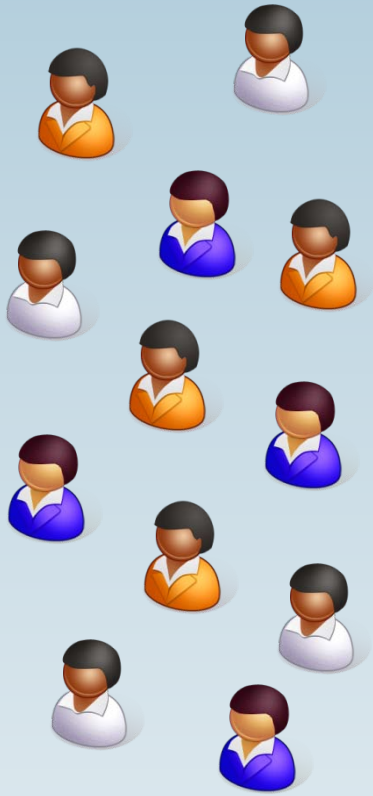
# How is this study better?

Unlike Flarend, this study:

- Includes **more volunteers** :
  - ✓ 12 volunteers similar to standard pharmaceutical studies
- Applies **more radiolabel** to **increase sensitivity**,
  - ✓ Still well within ethical guidelines
- Mimics **real life** exposure
  - ✓ Uses a roll-on like antiperspirant **formulation**
  - ✓ Tests at **high level consumer use** levels ($90^{th}$ percentile)
  - ✓ $^{26}Al$ is **homogenously** incorporated, meeting **commercial specification**
  - ✓ Armpits are not tape stripped or **occluded** with bandages
  - ✓ Shows whether normal **daily product** use alters skin absorption
  - ✓ Shows whether normal regular **shaving** affects skin absorption

# Study Design:
# Four Phases with 12 Volunteers

| | |
|---|---|
| Single Exposure | Similar to **Flarend Study**<br>Single dose of $^{26}$Al antiperspirant<br>No other antiperspirant use. No shaving. |
| Daily Use | **Daily antiperspirant use** including a single dose of $^{26}$Al antiperspirant.<br>No shaving. |
| Daily Use + Shaving | Daily antiperspirant use including a single dose of $^{26}$Al antiperspirant.<br>**Regular under arm shaving**. |
| IV Dose | Small intravenous dose of $^{26}$Al to allow **absolute bioavailability** to be calculated.<br>Each volunteer is their own **control** |



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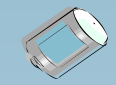
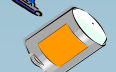

Daily Antiperspirant (without $^{26}Al$)


Regular Shaving


Antiperspirant test material (with $^{26}Al$)


Intravenous dose of $^{26}Al$

**Single Exposure**




| Week 1 | Week 2 | Week 3 | Week 4 | Week 5 |
|---|---|---|---|---|

**Daily Use**




| Week 6 | Week 7 | Week 8 | Week 9 | Week 10 |
|---|---|---|---|---|

**Daily Use + Shaving**

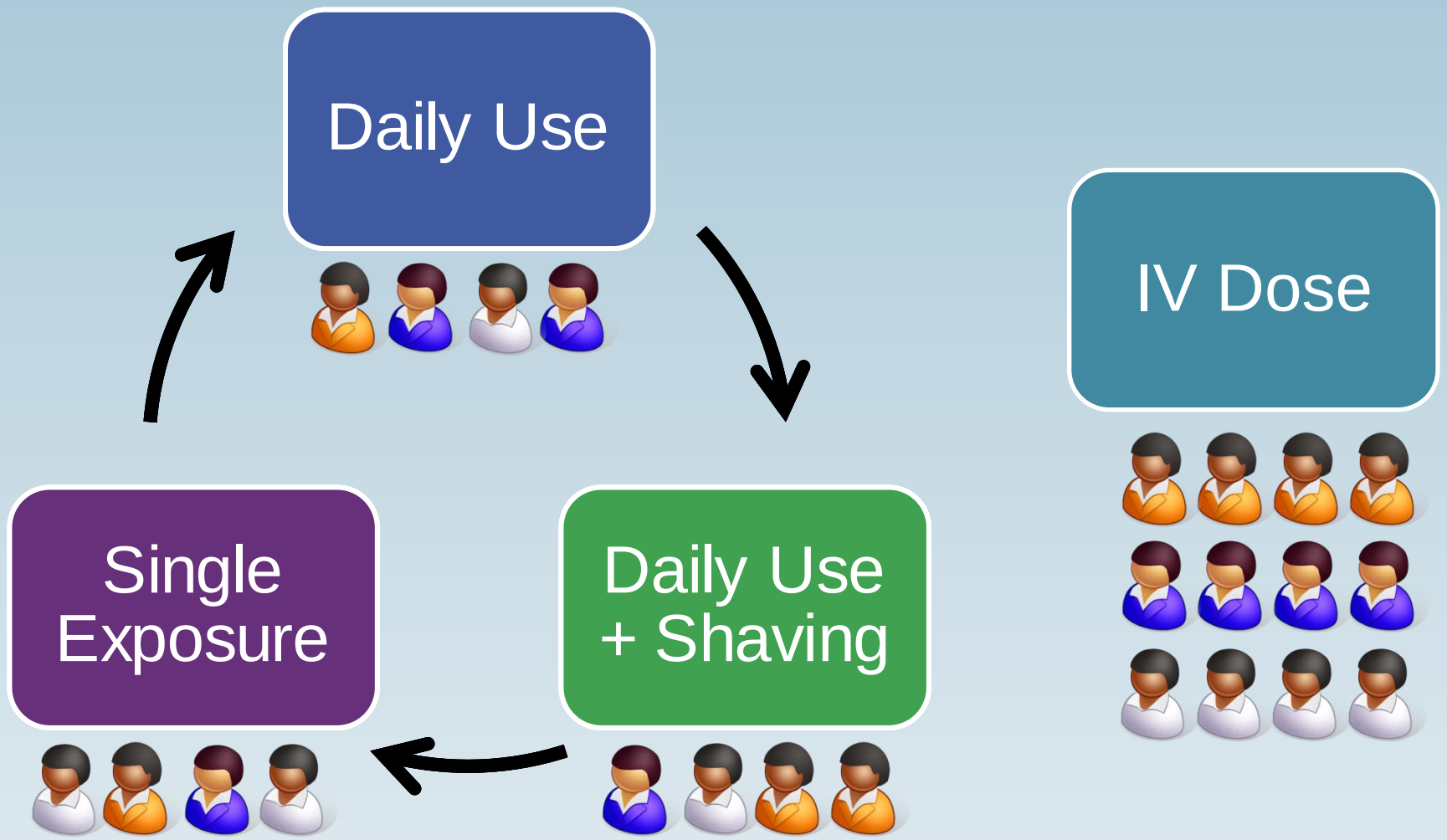



| Week 11 | Week 12 | Week 13 | Week 14 | Week 15 |
|---|---|---|---|---|

**IV Dose**


| Week 16 | Week 17 | Week 18 | Week 19 | Week 20 | Week 2 |
|---|---|---|---|---|---|

# Study Design:
# Randomised cross over design of study phases



# Conclusion

- No **credible evidence** to link cosmetic exposures to ill health
- Cosmetics' **contribution** to total consumer exposure to aluminium is **very low.**
- The Cosmetics Industry has commissioned a **study**, using the most **robust scientific techniques** to increase strength in the scientific basis in the **exposure** assessment of aluminium from antiperspirant products.
- Based on the available science, we are confident that our products are **safe for consumers to use**.

# Cosmetics Industry remains confident: Exposure to Aluminium from Cosmetic Products is Negligible

*Dr Dagmar Bury and Dr David Mason, Cosmetics Europe / Aluminium Consortium*

Aluminium is present in a number of cosmetics. The majority of these products use aluminium containing ingredients that are practically insoluble, so the aluminium is not free to be absorbed across the skin; these include insoluble pigments or naturally occurring clays and minerals (aluminium is the third most abundant element in the earth's crust). Some aluminium may also be ingested in lipstick or toothpaste residue; however these residues are very small compared to the total aluminium found in the diet. Antiperspirants contain soluble aluminium salts, however, as these form insoluble complexes with sweat on the surface of the skin, exposure is negligible.

Aluminium salts are a crucial ingredient in antiperspirants and have been used for many years. They form an insoluble gel when the aluminium salt mixes with sweat on the skin's surface, forming temporary plugs within sweat ducts. The formation of insoluble gel means that absorption across the skin is negligible since the soluble antiperspirant is rendered practically insoluble by the neutral pH of sweat or tissue fluid.

Safety risk assessments for antiperspirants have drawn together the evidence from detailed reviews of hazard data by the World Health Organisation (WHO 2011) and the European Food Safety Authority (EFSA 2008); together with estimates of internal (systemic) exposure from a clinical study by Flarend *et al.* (2001). This demonstrates that antiperspirants make only a very small contribution to the aluminium absorbed from a normal healthy diet.

Some years after the Flarend clinical study, a routine skin absorption study was conducted using dead skin from human donors. The full report is not publically available, although some of the results have been published in the scientific literature (Pineau et al. 2012). The study found that no aluminium had passed across the skin, although it did find increased levels of aluminium in the upper layers of the skin due to the fact that aluminium like other metal ions binds to proteins. However, the study is not relevant to human risk assessment; the study is not valid as it does not meet the recognised standards, the behaviour of antiperspirants on dead non-sweating skin is likely to be vastly different compared to living skin, and methodological flaws mean that comparison between samples is not scientifically valid.

Recent assessments by the German and European authorities (BfR 2014, SCCS 2014) have confirmed that the weight of evidence suggests that antiperspirant use is not associated with cancer (see Mirick *et al.* 2002) or neurodegenerative disease. Both reviews note the limitations in the assessment of skin absorption, acknowledging the difference in results in the studies by Flarend and Pineau, and highlight the limitations in both; thus a more robust study to measure dermal bioavailability under real-life conditions will be carried out. This is not a simple task as it requires a unique study design and rare isotope of aluminium.

We represent a Consortium of companies, working with Cosmetics Europe- the European Cosmetics Trade Association, and have initiated this new clinical skin absorption study. The study is in progress at a well respected independent research organisation. It addresses the limitations of earlier studies and will provide a strong scientific basis for the exposure assessment of aluminium from antiperspirant products, allowing a more precise risk assessment.

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# Kosmetikindustrie weiter überzeugt: Exposition gegenüber Aluminium aus kosmetischen Mitteln vernachlässigbar

*Dr. Dagmar Bury und Dr. David Mason, Cosmetics Europe / Aluminium Consortium*

Aluminium kommt in einer Reihe von kosmetischen Mitteln vor. Die meisten verwendeten aluminiumhaltigen Inhaltsstoffe sind praktisch unlöslich, so dass das Aluminium nicht über die Haut aufgenommen werden kann. Dazu gehören unlösliche Pigmente oder natürlich vorkommende Tonerden und Mineralien (Aluminium ist das dritthäufigste Element in der Erdkruste). Sehr geringe Mengen Aluminium können auch über Lippenstifte oder Zahnpasta durch Verschlucken aufgenommen werden; die betreffenden Mengen sind jedoch sehr gering im Vergleich zu der Aluminiummenge, die über die Nahrung aufgenommen wird. Antitranspirantien enthalten lösliche Aluminiumsalze, die jedoch unlösliche Komplexe mit dem Schweiß auf der Hautoberfläche bilden. Damit ist auch hier die Exposition vernachlässigbar.

Aluminiumsalze sind ein wichtiger Inhaltsstoff von Antitranspirantien und werden bereits seit vielen Jahren verwendet. Sie bilden ein unlösliches Gel, wenn sich das Aluminiumsalz mit dem Schweiß auf der Hautoberfläche vermischt. Dadurch werden die Schweißkanäle vorübergehend verschlossen. Da das lösliche Antitranspirant durch den neutralen pH-Wert des Schweißes oder der Gewebeflüssigkeit in eine praktisch unlösliche Form überführt wird, ist die Aufnahme von Aluminium über die Haut vernachlässigbar.

Die Sicherheitsbewertungen von Antitranspirantien basieren auf detaillierten Auswertungen der zu Aluminium vorliegenden Daten der Weltgesundheitsorganisation (WHO, 2011) und der Europäischen Lebensmittelsicherheitsbehörde (EFSA, 2008), zusammen mit Abschätzungen der internen (systemischen) Exposition aus einer klinischen Studie von Flarend *et al.* (2001). Diese Bewertungen zeigen, dass die Aluminiumsalze aus Antitranspirantien nur in sehr geringem Ausmaß zu der aus einer normalen, gesunden Ernährung aufgenommenen Aluminiummenge beitragen können.

Einige Jahre nach der klinischen Studie von Flarend *et al.* wurde eine Routinestudie zur Hautabsorption mit Hautpräparaten von menschlichen Spendern durchgeführt. Der vollständige Bericht ist nicht öffentlich verfügbar, aber einige der Ergebnisse wurden veröffentlicht (Pineau *et al.*, 2012). Die Studie kam zu dem Ergebnis, dass kein Aluminium durch die Haut gedrungen war, obwohl erhöhte Aluminiumwerte in den oberen Hautschichten beobachtet wurden. Letzteres ist allerdings begründet durch die Tatsache, dass sich Aluminium, wie andere Metallionen, an Proteine bindet. Für die Risikobewertung beim Menschen kann diese Studie jedoch nicht herangezogen werden – sie ist nicht aussagefähig, weil sie die anerkannten wissenschaftlichen Standards nicht erfüllt. Das Verhalten von Antitranspirantien auf präparierter, nicht transpirierender Haut ist sehr wahrscheinlich deutlich anders im Vergleich zu vitaler Haut. Außerdem liegen methodische Schwächen vor, so dass der Vergleich zwischen den Proben wissenschaftlich nicht valide ist.

Neuere Bewertungen durch die deutschen und europäischen Behörden (BfR, 2014; SCCS, 2014) haben nach Auswertung der vorliegenden Daten bestätigt, dass die Verwendung von Antitranspirantien nicht mit Krebserkrankungen (siehe Mirick *et al.*, 2002) oder neurodegenerativen Krankheiten zusammenhängt. Beide Bewertungen verweisen auf die Mängel bei der Bestimmung der Hautabsorption, bestätigen die unterschiedlichen Ergebnisse in den Studien von Flarend und Pineau und betonen die Einschränkungen

bei beiden. Aus diesem Grund wird derzeit eine aussagekräftigere Studie durchgeführt, um die dermale Bioverfügbarkeit unter realistischen Bedingungen zu bestimmen. Dies ist eine nicht zu unterschätzende Aufgabe, da sowohl ein einzigartiges Studiendesign als auch ein seltenes und schwer zugängliches Aluminiumisotop benötigt wird.

Wir vertreten ein Konsortium von Unternehmen, die mit Cosmetics Europe, dem Europäischen Kosmetikverband, zusammenarbeiten, und haben diese neue klinische Studie zur Hautabsorption initiiert. Diese Studie wird zurzeit von einem anerkannten unabhängigen Forschungsinstitut durchgeführt. Sie berücksichtigt die Mängel früherer Studien und wird eine verbesserte wissenschaftliche Grundlage für die Expositionsbewertung von Aluminium aus Antitranspirantien liefern und damit eine exaktere Risikobewertung ermöglichen.

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