

DATABOOK 2023

ALUMINIUM IN COSMETICS



LES ÉDITIONS DE L'OBSERVATOIRE DES COSMÉTIQUES

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It has been the subject of controversy for years, it returns particularly to the forefront of controversial ingredients when it is present in cosmetics in the form of salt. Is aluminium dangerous when applied to the skin? Is it in danger of being more strictly regulated? What are the alternatives available to formulators to address growing consumer concern? Is it possible to claim “Aluminium-free”? CosmeticOBS has gathered in this databook the different for and against arguments, and all the necessary data to understand aluminium in cosmetics...

Aluminium, antiperspirants, deodorants, and other products

It is controversial, but also daily and ubiquitous... and in fact not so well known. Which consumer who wants to avoid aluminium in his cosmetics really knows what he wants to avoid, and in what form would aluminium possibly have reasons to be avoided? And for what reasons? And in which types of products? How many people know how to explain the difference (and this applies to consumers as much as to some professionals) between deodorants and antiperspirants, and which ones may or may not contain aluminium salts? A brief reminder of the basics, to put the points on the i's of the word aluminium...



ALUMINIUM AND COSMETICS

It is in cosmetics, as it is ... everywhere. Almost never pure in nature, it is present as salts, mainly, and stirs up controversy. Many do not know what they talk about. What is aluminium? Where is it? What is its use? What are its dangers? What is its regulation? Let us make the point.

Aluminium is a ubiquitous chemical, meaning that it is present everywhere. It is the third element of the earth's crust by weight (eight per cent), after oxygen and silicium.

In nature, it is almost never found as a pure element. It is generally combined with molecules, organic (citrates, carboxylic acids, sucralfates ...) or mineral (chlorides, nitrates, sulfates, silicates ...). It comes as ore, such as bauxite, from which aluminium is extracted on an industrial scale. Aluminium is also found in clay (aluminium silicates) or in stone alum (double aluminium and potassium sulfates) ... then, generally as aluminium salts.

Aluminium is everywhere

Hence, we are, day after day, in direct contact with these aluminium salts. Exposure sources are numerous.

In nature:

- direct contact with soils,
- breathing ambient air,
- eating vegetables grown in soil (tea, cabbage, salads, other vegetables ...), or drinking spring water ...

Industrial uses of aluminium multiply the sources of exposure to this metal through different ways:

- housing: doors, windows made of aluminium,
- transports: bicycles, trains ...,
- food: additives, preservatives, colourants ...,
- drinking water treatment,
- packaging: containers, cans ...,
- kitchen utensils,
- pharmacy: anti-acid drugs (gastric diseases), adjuvanted vaccines, pharmaceutical glassware ...,
- medicine: surgical equipment (orthopaedic, dental ...), intravenous drips (especially hemodialysis, parenteral nutrition ...),
- cosmetics: anti-perspirants, mainly, but also alum-stone (natural or synthetic) based deodorants, clay-based masks and other cares for face and body, make-ups, sunscreens, oral products, tooth-pastes ...

Exposure doses

For every source, obviously, its specific exposure dose and, above all, a different bio-availability: when it is 100% for drips (aluminium is directly injected in blood), it is valued at 0.3% in drinking water, and from 0.1% to 0.3% for food.

The European Food Safety Authority (EFSA) has set a weekly acceptable dose of 1 mg per kilogram for human beings. As per Françoise Audebert, a toxicologist in the French FEBEA, the daily ingestion of aluminium (through food, additives, drinking waters, drugs ...) is guessed to be in the 35-50 mg range per person. The cosmetics would weigh between three to nine per cent of the acceptable dose for food.

Aluminium toxicity

In this area, the dose is a major factor. Aluminium toxicity has been demonstrated for important exposure to high doses. Keep in mind it is always a chronic toxicity (after exposure to repeated doses of aluminium), as an acute toxicity has never been reported.

In animals

Cases of neurotoxicity (action on the nervous system) have been reported during many studies on animals, along with effects on weight, testicles, embryos and on the development of the nervous system after oral exposure to aluminium.

Françoise Audebert thinks that these studies are biased and cannot be easily interpreted. Nevertheless, they have been the basis to set the acceptable doses for food.

In humans

In its **Evaluation of the risk linked to the use of aluminium in cosmetics** (October 2011), the French Afssaps writes that “the effects in humans (neurotoxicity, bone disease, anemia) are known in patients with renal insufficiencies who are chronically exposed to aluminium, as in premature babies fed by parenteral means.”

Françoise Audebert has confirmed this during a meeting on aluminium organized by the FEBEA on 20 April 2012, speaking about the reported cases of encephalopathy in dialyzed people and patients with renal insufficiencies, as well as about the cognitive disorders in workers coming after an occupational exposure through respiratory route.

Cases of osteodystrophy (a bone disease) have been reported in dialyzed patients. These effects are reported for extremely high doses of aluminium in blood, in the 30 to 80 µg per liter.

A case of serious anemia, tiredness and bone aches has been reported by a team of French researchers in 2004 in a woman who made a daily use of an anti-perspirant containing an aluminium salt (aluminium chlorhydrate). When she stopped using this product, the aluminium concentration measured in her blood plasma and in urine lowered ... and aches stopped.

However, this study is questioned by the cosmetic industry, which says it is a unique case, never confirmed by another report. Further, it argues that there are some methodological biases.

Aluminium and breast cancer

The suspicion of a link between exposure to aluminium (especially through anti-perspirants) and breast cancer was born at the very beginning of the 2,000 decade. It is regularly revived, as in 2004 by a study by Dr Darbre, and, more recently, after an *in-vitro* **research by a team from the Geneva University**, but it is every time undermined by the sanitary authorities.

For instance, in its 2011 evaluation, the French Afssaps stays on the position that “animal testing does not give any proof of carcinogenic potential. Epidemiological data do not allow for the establishing of a conclusive link between cutaneous exposure to aluminium and the development of cancer.”

Aluminium and Alzheimer

Another persistent suspicion: the link between aluminium and Alzheimer’s disease. Its origin dates back to 1994, when a team of British researchers published results showing that the brain cells of patients who had Alzheimer’s disease contained ten to thirty more aluminium than average. A fact, more than a cause-to-effect link, but which has been enough to raise doubt and worry.

Once again, the sanitary authorities the world over go in the same direction:

- The WHO concludes there is no conclusive cause-to-effect link.
- Canada Health, the federal minister for prevention and promotion of health, states in 2001 that “the results of the research that let it know there is a correlation between the accumulation of aluminium in

the body and the Alzheimer's disease are not considered as conclusive.”

• A common report by three French health agencies, the Afssaps, the INVS and the Afssa, in 2003 affirms that “no causal relationship can be reasonably thought of.”

These opinions have been supported in 2005 in Germany, and again in France in 2008. This same year, the European EFSA adds the food exposure (by far, the most important) is not a risk for the development of the disease.

Aluminium and the regulation on cosmetics

The fact is that aluminium could be harmful to the human health. We could think, at least by the name of the principle of precaution that it is strictly regulated and that limits are set to its use.

Note that, from the food side, an “acceptable” dose (the only one that is defined) is not the maximum allowed dose.

When looking for references to aluminium in the documents that deal with cosmetics in Europe (the current Directive, or the Regulation that will completely replace it in July 2013), one finds ... not so much.

- In the Annex III of the Regulation that deals with the cosmetic ingredients subject to restrictions for use, the first quoted aluminium derivative is aluminium fluoride, with a limit of 0.15% in oral care. However, this percentage is applied for fluorine, and the aluminium element is not really of concern.
- In this same Annex, one can see the hydrated aluminium and zirconium hydroxychlorides. In anti-perspirants, the limit is set at 20% (calculated as anhydrous aluminium and zirconium hydroxychloride) and at 5.4% (zirconium). Once again, aluminium is not the concern; it is zirconium (its use is banned in cosmetics, apart for some exceptions, as this one). The other aluminium salts may be used without any restrictions.
- Again in the Annex III, there is a limit for the concentration of dyes in non-oxidative hair colourants (the limit is set between 0.4 and 0.5%.)
- As a final point, some aluminium is present in the list of colourants allowed in cosmetics (Annex IV of the Regulation), again without any restrictions for use.

May this kind of aluminium, which may be found in any type of cosmetic products, without any limitation, be harmful to the human body?

Dosage and way into the body

The main questions, by far, are if, how and in which quantity cosmetic aluminium may go through the cutaneous barrier and enter the human body.

That is not that simple.

Even if the healthy/damaged or shaved skin, or healthy skin/skin whose unwanted hair has been removed (obviously, aluminium will enter more easily through an aggressed skin) problem is put aside, measuring the percutaneous crossing of this element is not an easy task.

First, aluminium salt is not equivalent to pure aluminium (as an example, 20% aluminium chlorohydrate is equivalent to 5% aluminium). Thus, it is necessary to know what is measured ...