

Risk assessment related to the use of aluminum in cosmetic products

Summary

The safety of aluminum uptake from food-contact articles, medicinal and cosmetic products is frequently questioned. It is particularly incriminated in the development of Alzheimer's disease. In 2003, a common scientific opinion from the French health and safety agencies, entitled "Assessment of health risks related to exposure of the French population to aluminum" (AFSSAPS/AFSSA/INVS, 2003) was published. This opinion highlighted the lack of relevant data on dermal absorption of cosmetic products containing aluminum.

In 2004, Darbre et al. (2003) published works indicating a link between the use of underarm cosmetics such as aluminum-based antiperspirants and breast cancer.

Following a request from the Directorate General for Health, the Afssaps was requested to provide a scientific opinion on the safety of aluminum from cosmetic sources.

The present risk assessment takes into account both the recent dermal absorption study provided by industry and summarized toxicological data, partly based on the recent opinion provided by the European Food Safety Authority (EFSA, 2008b).

More than twenty-five aluminum compounds can be used in cosmetic products. The aluminum chlorohydrate is one of the most widely used, especially as antiperspirant.

The oral bioavailability of the aluminum ion from drinking water in humans and experimental animals was estimated to be in the range of 0.3%, whereas the bioavailability of aluminum from food and beverages is generally considered to be lower, about 0.1%. Widely distributed throughout the body, aluminum can enter the brain and reach the placenta and fetus. Its half-life is very variable according to studies and can reach several years when administered chronically. Its elimination is mainly renal.

The absorption of aluminum after dermal exposure is very poorly understood. The available studies are of poor quality and are not carried out according to the current requirements. The recent *in vitro* study on human skin allowed to estimate the dermal absorption. In this study, the estimated quantities of aluminum absorbed via a daily exposure to an antiperspirant containing 20% of aluminum chlorohydrate (5% aluminum) were obtained using two scenarios.

The first scenario corresponds to the exposure of intact skin, and leads to a dermal absorption rate of 0.5%; the second scenario corresponds to the exposure of damaged skin, and results in an absorption rate of 18%. Thus it is of 2.1 mg Al/kg bw./d. in the first scenario and 75 mg Al/kg bw./d. in the second scenario. In conclusion, the margin of safety is 11 in intact skin exposure conditions and less than 1 in the case of damaged skin exposure conditions.

The irritant potential of aluminum is insufficiently studied in animals. However, cases of skin irritations associated with cosmetic products containing aluminum chlorinated compounds were reported in humans. Additional data would be needed to confirm the risk of irritation associated with these products. Cases of sensitization are rare.

Repeated dose administration in laboratory animals showed that several aluminum containing compounds have the potential to produce neurotoxicity (mice, rats) and to affect the male reproductive system (dogs). In addition, after maternal exposure, embryotoxicity (mice) was observed and the developing nervous system in the offspring (mice, rats) (EFSA, 2008) was affected. Contrary to the EFSA assessment, the Afssaps retained the NOAEL of 22 mg/kg bw./d., obtained in a study performed in dogs and based on a decreased body weight and histopathological changes of the kidney and liver.

Human effects (neurotoxicity, anemia ...) are known in patients undergoing dialysis and thereby chronically exposed parenterally to high concentrations of aluminum, as well as in premature infants fed by parenteral route. Systemic dose of 5 mg Al/kg bw./d. is considered safe by the Food and Drug Administration for the use of parenteral fluids for two populations with reduced kidney function as premature infants and patients with renal impairment.

The EFSA noted that the indirect mechanisms of genotoxicity, occurring at relatively high levels of exposure, are unlikely to be of relevance for humans exposed to aluminum via the diet. In addition, the animal studies did not show any carcinogenic potential. More, epidemiological data do not establish any conclusive link between dermal aluminum exposure and development of cancer. In conclusion, there are insufficient data to establish a clear relationship between the use of underarm aluminum-based antiperspirants and breast cancer.

This risk assessment shows that exposure to antiperspirant products with concentrations of 20% aluminum chlorohydrate does not ensure consumer safety under normal conditions of use.

In addition, as the present risk assessment does not take into account the total exposure to various cosmetic products likely to contain aluminum, these conclusions are subject to change thereafter, based on an assessment taking into account the different product categories and their uses. Specific data to other exposure conditions (quantities, dermal absorption, toxicity) could be provided to refine the risk assessment related to the use of aluminum in other cosmetic products.

In conclusion of this risk assessment the Afssaps recommends:

- **to restrict** the concentration of aluminum in cosmetic products at **0.6%**. This value is deliberately expressed in aluminum, so that it can apply to different used forms in cosmetic products;
- **not to use** cosmetics containing aluminum on **damaged skin**. Indeed, given the high absorption reported in these conditions, it is necessary to inform consumers that antiperspirants or deodorants products containing the aluminum should not be used after shaving or if the consumer's skin is affected by small cuts. The Afssaps recommends this information to be clearly indicated on the packaging.

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