Updated Fact Sheet on Aluminium and Health

Prepared for:

Aluminium REACH Consortium/International Aluminium Institute

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Contents

Updated Fact Sheet on Potential Adverse Health Effects from Exposure to Aluminium and Aluminium Compounds[1]

This Fact Sheet is based on a comprehensive assessment of the scientific literature on the potential health effects of aluminium. Over five years have passed since the first Fact Sheet was developed and new information on the potential adverse health effects of aluminum compounds has become available. The Fact Sheet, developed and written by external consultants, has been updated based on the current scientific data.

Introduction

This Fact Sheet provides a comprehensive summary of the current scientific evidence for potential health effects from aluminium (Al), aluminium oxide (Al_2O_3), and aluminium hydroxide ($Al(OH)_3$) under typical conditions of exposure. The information provided is based on recent reviews of published peer-reviewed studies in which possible adverse **health effects** from exposure to these substances (by workers, **downstream users**, customers and the general public) have been investigated. Definitions for words in **bold font** can be found in the glossary at the end of the Fact Sheet.

About Al, Al_2O_3, and $Al(OH)_3$[1,2,3]

Aluminium (chemical symbol: Al) is ubiquitous in the environment and makes up close to 8% of the Earth's crust by weight. Aluminium is light and resistant to corrosion. Bare aluminium metal is highly reactive and its surface is oxidised immediately on contact with air to form an inert coating of aluminium oxide (chemical formula: Al_2O_3). Al_2O_3 is very hard and poorly soluble in water. In its crystalline form, corundum, it is used as an abrasive and refractory material. Aluminium hydroxide (chemical formula: $Al(OH)_3$) is the main component of bauxite, a naturally occurring mineral that is the primary source in the manufacture of aluminium metal.

How might I be exposed to aluminium?

People can be exposed to aluminium in the following ways:

- through the air (in dust from soil);
- through consumption of food (natural sources, food additives, or minor amounts leached from utensils or food packaging);
- through drinking water (natural sources or small amounts of an aluminium-containing flocculant used in water purification);
- through the use of some consumer and pharmaceutical products (e.g., anti-perspirants and aluminium-containing antacids); and
- in the workplace if employed as aluminium welders or in the production or handling of aluminium substances (workplace exposures occur mainly by inhalation).

The solubility of aluminium and aluminium substances in water is an important factor in determining the amount of **aluminium ion** that actually enters the bloodstream, a quantity known as

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bioavailability. Aluminium, aluminium oxide and aluminium hydroxide are poorly soluble in water.[4,5,6] Less than 0.1% of these substances is absorbed while passing through the gastrointestinal tract.[7,8] Only a small fraction of these substances is absorbed after being inhaled.[9] The scientific evidence, including a study in humans,[10] also suggests that aluminium and its insoluble compounds have very limited ability to penetrate the skin,[11] indicating that the bioavailability of aluminium following dermal exposure is very low.[8]

What does the science say about aluminium and health effects?

Neurological Effects

Dialysis encephalopathy, a degenerative neurological syndrome, was observed in patients on kidney dialysis who had been exposed to very high levels of aluminium in contaminated dialysate and phosphate-binders. Changes in dialysis procedures have now eliminated this problem.[12]

An area of continuing debate is the possible role of aluminium in the development and progression of **Alzheimer's Disease** and possibly other **neurotoxic effects** that may contribute to declines in cognitive function with age.

Based on the available scientific literature, neurotoxic effects are not expected at the levels of aluminium to which the general public is typically exposed.[13]

A recent **guideline study**[14,15] has demonstrated mild neurological effects in rats exposed to high levels of aluminium. These effects were only observed at aluminium levels a thousand-fold higher than what is typically found in treated drinking water and food.[15]

Recent well-conducted studies investigating whether there is a link between aluminium levels in drinking water and Alzheimer's Disease have provided inconclusive results.[16]

Considering all sources of evidence related specifically to Alzheimer's Disease, the current **weight of evidence** does not support a primary role for aluminium in causing this condition.[17]

The potential role of aluminium in other diseases involving cognitive decline is under active investigation. At present, there is no clear evidence that such effects are caused by aluminium.

Worker exposures to aluminium are controlled by regulatory standards. The weight of evidence, which is strongly influenced by recent occupational studies[18,19] does not support a neurotoxic **risk** to workers exposed to airborne aluminium, or aluminium oxide and aluminium hydroxide dusts in workplaces which conform to regulatory standards.[1-3, 20]

Effects on the Lungs

There is currently no evidence for a chemical-specific **respiratory (fibrogenic) effect** due to exposure to aluminium metal powder.[21,22]

When not appropriately controlled, several airborne substances in pot-rooms may contribute to an irritation effect in the lungs.[23] The evidence points to a role for fluoride-containing substances[12,24,25,26] or sulphur dioxide.[26] The available evidence suggests that aluminium oxide and aluminium hydroxide behave as "**nuisance dusts**" under current controlled occupational exposure conditions.

Results from workplace studies do not demonstrate allergic reactions or lung sensitisation associated with exposure to aluminium compounds.[27] The weight of evidence, supported by negative results from animal dermal **sensitisation** studies,[28,29] does not suggest a **sensitisation potential** for aluminium metal, aluminium oxide, and aluminium hydroxide dusts through inhalation exposure.[30]

Effects on Fertility

The weight of evidence, including considerations of bioavailability and results from animal studies, does not indicate effects on reproduction.[1-3,14,15,31,32]

Effects on Infants and the Developing Foetus

The available data, including considerations of bioavailability and negative results from animal studies on soluble aluminium salts, do not support a risk of developmental effects in humans on exposure to aluminium, or aluminium oxide and aluminium hydroxide dusts.[1-3,12,13,24,31,32]

Cancer

The weight of evidence from human, animal, and *in-vitro* studies does not support a cancer **hazard** in humans associated with exposure to insoluble aluminium metal, aluminium oxide, or aluminium hydroxide by the oral, inhalation, or dermal routes.[1-3, 21,33,34]

Although the process of "Aluminium Production" has been classified by IARC[35,36] as Group 1 (Carcinogenic to Humans), this does not imply that aluminium *per se* is the responsible agent. The evidence supports a role for known **carcinogens,** such as polycyclic aromatic hydrocarbons (PAHs)[37] in the workplace, rather than a role for aluminium in this effect.[13,33,38]

The weight of evidence from several epidemiological studies does not support an association between breast cancer and aluminium-containing antiperspirants.[12,13,29,40]

The weight of evidence, including considerations of bioavailability and negative results from recent **guideline studies,**[41] also does not support a **mutagenic or genotoxic** hazard from human exposure to aluminium, or aluminium oxide and aluminium hydroxide dusts by the oral and inhalation routes.[1-3, 12,13]

Other Effects

Aluminium is present in the human diet. For adults, the daily intake of aluminium has been estimated at about 2.5-13.5 mg (0.035 – 0.19 mg per kilogram body weight per day for 70 kg adults) and can be much higher (500 mg or more; 7.14 mg per kilogram body weight or more for 70 kg adults) in individuals taking antacids containing aluminium hydroxide.[42] Normal dietary levels of intake of aluminium are not associated with acute or long-term adverse health effects.[13,33]

Case reports of sensitisation by aluminium following exposure of the skin are rare.[43,44] A recent guideline study in animals exposed to aluminium hydroxide was negative,[45] as was an industry-sponsored study in which aluminium oxide was investigated.[46] The weight of evidence suggests limited sensitisation potential for aluminium metal, aluminium oxide, and aluminium hydroxide dusts following dermal exposure.[1-3,13,33,47]

The Hazard Classification of the Target Aluminium Substances

Aluminium metal, aluminium oxide and aluminium hydroxide are not classified for any hazard class according to Regulation (European Commission) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures and the United Nations' Globally Harmonised System of Classification and Labelling of Chemicals (GHS).[1-3]

Further Research

Although the potential health effects of aluminium have been subject to extensive scientific evaluation, further research in certain areas is warranted. Further data on the **pharmacokinetics** of aluminium is needed. Potential interactions between aluminium and other metals such as iron, copper, and zinc should also be investigated.

Overall Summary

Aluminium is the most abundant metallic element on Earth. It is present in the human diet at moderate levels, less than 15 mg being ingested daily. Aluminium metal is used as a structural material in the construction, automotive, and aircraft industries, in the production of metal alloys, in the electrical industry, in cooking utensils, and in food packaging. Aluminium compounds are used as coagulants with beneficial effects in water treatment, as antacids, antiperspirants, and food additives.

A number of different organisations have suggested dietary intake limits for aluminium. A recent decision by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) established a provisional tolerable weekly intake (PTWI) of 2 mg aluminium per kilogram body weight or 0.29 mg aluminium per kilogram body weight per day. The PTWI applies to all aluminium compounds in food, including food additives.[49]

This fact sheet provides a summary of the evidence for potential health effects from aluminium (Al), aluminium oxide (Al_2O_3), and aluminium hydroxide ($Al(OH_3)$) under exposure conditions typically found in the workplace, in the general environment, and in the diet. At current exposure levels, based on the available data, there is no evidence that these compounds are associated with adverse health outcomes in the general population.

Appendix 1. Glossary

Alzheimer's Disease: Alzheimer's Disease (AD) is a progressive, degenerative disease of the brain, which causes thinking and memory to become impaired. It is the most common form of dementia. Dementia is a syndrome consisting of a number of symptoms that include loss of memory.
(For further information see: http://www.alzheimer.ca/english/disease/intro.htm).

Bioavailability: The quantity or fraction of a chemical that actually enters the blood stream.

Carcinogen: An agent that increases the risk of cancer in humans.

Dialysis Encephalopathy: A degenerative neurological syndrome, characterized by the gradual loss of motor, speech, and cognitive functions.

Downstream users: Companies or individuals who use a substance, either on its own or in a mixture, in their industrial or professional activities
(For further information see: https://echa.europa.eu/regulations/reach/downstream-users/about-downstream-users/who-is-a-downstream-user).

Fibrogenic Effect: An adverse health effect associated with the development of fibrous tissue in the lungs, resulting in a loss of the tissue's ability to transfer oxygen into the bloodstream.

Gastrointestinal Irritation: A condition associated with irritation and inflammation of the stomach and intestines. The main symptoms are gastric and/or abdominal pain, mild to moderate diarrhoea, and nausea, with or without vomiting.

Genotoxicity: The capacity of a chemical or an agent to alter genetic material (DNA) in living cells.

Guideline Study: A study conducted according to an internationally agreed upon testing method, such as the OECD Test Guideline established by the Organization for Economic Cooperation and Development (OECD).

Hazard: "The intrinsic property of the agent that makes it capable of causing adverse effects to occur in humans or the environment, under specific conditions of exposure." (For future information see: http://www.hc-sc.gc.ca/ahc-asc/alt_formats/hpfb-dgpsa/pdf/pubs/risk-risques-eng.pdf).

Metal Ion: A metal is an element, compound, or alloy characterized by a capacity to conduct electricity and heat. Metal ions (specifically cations - positively charged ions) are formed by electron loss.

Mutagenicity: The capacity of a chemical or an agent to induce or increase the frequency of mutation in an organism.

Neurotoxic Effect: An adverse effect on nervous system cells and tissues associated with pathological changes in the structure or function of the nervous system.

Nuisance Dusts: Dust particles which are poorly soluble in water and have low sensitization potential and toxicity (other than by inflammation or the mechanism of "lung overload").

Pharmacokinetics: The quantitative assessment of the movement of chemicals within the body following exposure.

Risk: "A measure of both the harm to human health that results from being exposed to a hazardous agent, together with the likelihood that the harm will occur." (For future information see: http://www.hc-sc.gc.ca/ahc-asc/alt_formats/hpfb-dgpsa/pdf/pubs/risk-risques-eng.pdf).

Skin Sensitisation: Skin sensitisation (allergic contact dermatitis) is an immune response to an environmental agent. In humans, sensitization responses may be characterised by pruritis (itching), erythema (redness), oedema (swelling), and blisters.

***Sensitisation Potential*:** The ability to cause an allergic reaction that results in the development of hypersensitivity (a condition in which the allergic response to a second or later exposure is greater than the response to the first exposure to the substance) to an environmental agent.

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