Office for Product Safety & Standards

SCIENTIFIC ADVISORY GROUP ON CHEMICAL SAFETY OF NON-FOOD AND NON-MEDICINAL CONSUMER PRODUCTS

Final opinion on aluminium in toys or components of toys.

1. Background

1.1 Current migration limits for aluminium (CAS No. 7429-90-5) in toys are based on a tolerable daily intake (TDI) of 0.75 mg/kg bw/d (RIVM, 2008).

1.2 The European Food Safety Authority (EFSA) (EFSA, 2008) and the Joint Food and Agriculture Organisation of the United Nations and the World Health Organisation (FAO/WHO) Expert Committee on Food Additives (JECFA) (WHO, 2011) have each established tolerable intake levels for aluminium that are notably lower than the level that was the basis for the migration limits for aluminium in the Toy (Safety) Regulations 2011.The current limits are outlined in Table 1 below.

1.3 In light of the new evidence presented in the EFSA and JECFA scientific opinions, the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) highlighted the study by Poirier *et al.* (2011) as fundamental for the derivation of a health-based limit value. A TDI of 0.3 mg/kg bw/d was deemed appropriate and newly proposed aluminium migration limits from toys are outlined in Table 1.

Table 1. Current and proposed migration limits for aluminium in three different types of toy material (SCHEER, 2017).

	Migration Limits (mg/kg)					
Element	**Dry, brittle, powder-like or pliable toy material**		**Liquid or sticky toy material**		**Scraped-off toy material.**	
Aluminium	Current	Proposed	Current	Proposed	Current	Proposed
	5625	2250	1406	560	70000	28130

1.4 The SCHEER noted that exposure to aluminium from sources others than toys, in particular from the diet, which is by far the major source of chronic exposure, may already exceed the reference value for tolerable weekly intake as derived by JECFA. Therefore, the SCHEER recommends that the additional exposure from toys should be minimised.

1.5 Drinking water represents an additional, although minor, source of chronic exposure.

1.6 Intermittent exposure from the use of aluminium compounds in consumer products (e.g. cosmetic and antiperspirant via dermal absorption) or exposure via inhalation, related to dust can occur. In addition, there may also be intermittent exposure to aluminium from pharmaceuticals via the oral and parenteral route.

1.7 Food contact materials also represent an additional route of exposure. Cooking in aluminium containers or preserving food in aluminium containing cans or pots often results in statistically significant, but not biologically important, increases in the aluminium content of some foods.

1.8 Inhalation of aluminium in ambient air represents a small contribution to an individual's exposure. Dusts arising from soil, especially in industrial or agricultural areas, and from the metal surfaces of air conditioners can contain measurable amounts of aluminium, resulting in high localized concentrations and, subsequently, in higher exposures. However, for the general population, inhalation is likely to be less important as an exposure pathway than is dietary exposure.

1.9 Further details relating to exposure sources of aluminium can be seen in section 5.4 of the 2017 SCHEER opinion on aluminium.

1.10 Aluminium has a strong affinity to oxygen (SCHEER, 2017). Therefore, it is almost never found in the elemental state. It can be found as aluminium derivatives with:

- Chloride (used in the manufacture of rubbers and lubricants, and as an antiperspirant).

- Hydroxide (used as an adsorbent, emulsifier, ion-exchanger, mordant in dyeing, and filtering medium, flame retardant in different materials, including children's toys and clothing (e.g. pyjamas), Detergents and as a vaccine adjuvant).

- Phosphorus (used for cosmetics, paints and varnishes, pharmaceuticals (antacid), vaccine adjuvants, emulsifying agent in pasteurized processed food and in refrigerated or frozen products).

- Sulphur for water purification, vaccine adjuvants.
- Other aluminium compounds that are used as food additives include aluminium silicates (anticaking agents) and aluminium oxide, used in the manufacturing of ceramics, in electrical insulators, and as a food additive (dispersing agent)

2. Presentation and discussion by the Scientific Advisory Group on Chemical Safety of Non-food and Non-Medicinal Consumer Products (SAG-CS)

2.1 At the meeting held 18.05.21, the SAG-CS considered "SAG-CS-052102 Aluminium in toys or components of toys" which focussed on revisions to the migration limits of aluminium in dry, brittle, powder-like or pliable toy materials, liquid or sticky toy materials, and scraped-off toy materials. The proposed changes were outlined in Table 1.

2.2 Members expressed their satisfaction with the analytical methods used to determine migration limits and stated that the limit of detection and limit of quantification (LOD and LOQ, respectively) of the relevant methods were adequately below the newly proposed limits.

2.3 Members discussed a key evidential paper (Poirier *et al.*, 2011) in-depth, which was used as the basis for setting the TDI for aluminium. The study in question was a 12-month neurodevelopmental toxicity study undertaken using aluminium citrate in rats which was performed to Good Laboratory Practice (GLP).

2.4 Members agreed that the study was conservative owing to the use of a highly absorbable aluminium salt (citrate) and the sensitive neurodevelopmental marker. Members expressed difficulty in locating a clear dose-response relationship from the study. Members concluded that, with only three doses presented, there could also be difficulties in the interpretation of a benchmark dose assessment from the study.

2.5 A further relevant study which was not included in the SAGCS-052102 paper was brought to the attention of the group and discussed (Golub and Germann, 2015). Members reviewed this study to ensure that nothing presented in the paper would alter the views of the Committee.

2.6 Members were asked if they were aware of any other publications beyond those discussed, or presented in the SCHEER opinion for a further summation of relevant literature that may influence the SAGCS opinion.

2.7 Members did not refer to further publications other than those referenced below. In summary, following a subsequent review of the SCHEER, the group were content with their final recommendations. The group noted that in the final opinion of SCHEER it states that when estimating the total exposure of infants and children to aluminium, it is important to take into account all significant sources of exposure,

i.e. to include dietary exposure typical of different age groups and exposure from further specific sources. The uptake of aluminium from other voluntary sources, such as toys, should therefore be minimised

3. Terms of Reference

Members were satisfied that there was sufficient evidence to form an opinion at this stage.

Members agreed with the revised TDI and proposed migration limits for aluminium in toys and were satisfied with the analytical methods used to determine migration limits. Members agreed that the pivotal 12-month neurodevelopmental toxicity study, used to determine the TDI, was conservative owing to the use of a highly absorbable aluminium salt (citrate) and the sensitive neurodevelopmental marker.

Members agreed unanimously with the proposed TDI and migration limits.

Members expressed that the limits should be kept under review, with consideration given to any emerging data relating to the subject.

Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products

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