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TÜV Rheinland LGA Products – Information

November 2019

Adaptation of the Toy Safety Directive 2009/48/EC
Aluminium and Formaldehyde

Annex II Part III No. 13: Reduction of the migration limit for aluminium

The Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) has reviewed the available data on the toxicity of aluminium and is now regarding a tolerable daily intake (TDI) of 0.3 mg/kg body weight per day as an appropriate base for calculating the migration limits for aluminium from toys.

The maximum contribution from toys to the daily intake recommended by the Scientific Committee on Toxicity, Ecotoxicity and the Environment in its 2004 opinion is 10 %. Based on this data, SCHEER did a new calculation of the limit values: Multiplying 10% of the TDI by the average weight of a child under three years of age (estimated at 7.5 kg) and divided by the daily quantity of toy material ingested (data taken from the original RIVM Report).

Commission **Directive (EU) 2019/1922** of 18 November 2019:
https://eur-lex.europa.eu/eli/dir/2019/1922/oj?locale=en

	Category I	Category II	Category III
Limit values for aluminium	in dry, brittle, powder-like or pliable toy materials	in liquid or sticky toy materials	in scraped-off toy materials
Current	5 625 mg/kg	1 406 mg/kg	70 000 mg/kg
Future	2 250 mg/kg	560 mg/kg	28 130 mg/kg

The new limits will enter into force on **20 May 2021**.

The test method to be used shall be standard EN 71-3 (Safety of toys - Part 3: Migration of certain elements) in the version EN 71-3:2013+A3:2018 (permitted until 15 April 2020) or EN 71-3:2019. From 15 April 2020, however, only EN 71-3:2019 will be the harmonised version (legally binding basis for presumption of conformity with the Toy Safety Directive).

Currently aluminium is used in the following toy materials:

- Metals (pure aluminium or alloys)
- Metal effect pigments from aluminium powder (e.g. C.I. Pigment Metal 1 = silver bronze)
- Color pigments with aluminum silicates (e.g. ultramarine blue: C.I. Pigment Blue 29, C.I. Pigment Violet 15)
- Clay minerals as fillers (e.g. kaolin) and/or binders (e.g. bentonite) in paper, plastics, porcelain, lacquers, paints, coloured pencil leads, etc.

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Annex II Appendix C: New Entry for Formaldehyde [CAS No 50-00-0]

Formaldehyde is classified as carcinogenic category 1B under Regulation (EC) No 1272/2008 (generic classification limit of 0.1%). Due to these properties, formaldehyde is also subject to the general prohibition of the Toys Directive for CMR substances according to Annex II Part III No. 3 of the Toy Safety Directive 2009/48/EC. Pursuant to point 4(a) of Part III of Annex II formaldehyde may be used up to a concentration of 0.1 %, which corresponds to 1 000 mg/kg (content limit).

The Expert Group on Toys Safety considered the existing rules to be inadequate, in particular for the following products:

- **Polymeric materials** such as formaldehyde resins (use of formaldehyde as monomer)
  Formaldehyde is absorbed from these materials by ingestion when monomers are released by saliva when mouthing the toy.
  The tolerable daily intake (TDI) for formaldehyde is 0.15 mg/kg bodyweight per day; toys should allocate only 10 % of the TDI. Assuming a daily oral intake of 100 ml saliva and a child with a body weight of 10 kg, a formaldehyde migration limit of 1.5 mg/l was recommended.
- **Resin-bonded wood products** such as particle board, oriented-strand board (OSB), high-density fibre board (HDF), medium density fibre board (MDF) and plywood (use of Formaldehyde resins as glue)
  Formaldehyde resins include phenol-formaldehyde (PF), urea-formaldehyde (UF), melamine-formaldehyde (MF) and polyacetal (polyoxymethylene - POM) resins.
  Intakte takes place mainly by inhalation of formaldehyde as gas that emitted from the product. To prevent sensory irritation as well as cancer, a room air limit value for formaldehyde emission of 0.1 ml/m³ has been set.
- **Textiles** (formaldehyde as finishing agent), **leather** (tanning, finishing) and **paper materials** (biocide, glue)
  Dermal exposure may cause allergic contact dermatitis; lowest threshold concentration is 30 mg/kg. Even the most sensitized individuals shall be protected.
- **Water-based toy materials** such as soap bubbles or inks in felt-tip pens, and also dry materials intended to be mixed with water prior to use (formaldehyde and formaldehyde releasing substances as preservative)
  Following the opinion of the Scientific Committee on Health and Environmental Risks (SCHER) that CMR compounds should not be present in toys, the recommended limit was close to the lowest value that can be reliably determined. The EDQM method for the determination of free formaldehyde in cosmetic products takes account of traces of formaldehyde up 10 mg/kg that certain other preservatives may release.

Therefore, specific limit values for formaldehyde in different toy materials have been established and included in Annex C. This applies to toys intended for use by children under 36 months of age or toys intended to be placed in the mouth.

Commission **Directive (EU) 2019/1929** of 19 November 2019:
https://eur-lex.europa.eu/eli/dir/2019/1929/oj

Toy Material	Limit Value	Test Method
polymeric material	1,5 mg/l (migration)	EN 71-10:2005 + EN 71-11:2005 (aqueous migrate)
resin-bonded wood	0,1 ml/m³ (emission)*	EN 717-1:2004 (test chamber)
textiles	30 mg/kg (content)	EN ISO 14184-1:2011 (aqueous extract)
leather	30 mg/kg (content)	EN ISO 17226-1:2008 (aqueous extract)
paper	30 mg/kg (content)	EN 645:1993 and EN 1541:2001 (aqueous extract)
water-based material	10 mg/kg (content)	EDQM (free formaldehyde in cosmetics)

*Corresponds to formaldehyde emission class E1 as defined in the harmonized European Standard EN 13986 for wood-based panels for use in construction

The new limits will enter into force on **21 May 2021**.

The requirements and test methods are partially identical to the requirements of the non-harmonized standard EN 71-9:2005+A1:2007 (Safety of toys - Part 9: Organic chemical compounds - Requirements):

Toy Material	**Limit value EN 71-9**	**Test Method EN 71-9**	**Comparison with Anlage C**
Polymeric	2,5 mg/l (migration)	EN 71-10:2005 + EN 71-11:2005 (aqueous migrate)	Same test method; higher limit value
Resin-bonded wood	80 mg/kg dry wood	EN 717-3 (WKI-flask method)	Different test method; other limit (Results are not comparable)
Textile	30 mg/kg (content)	EN ISO 14184-1:2011 (aqueous extract)	identical
Leather	30 mg/kg (content)	EN ISO 17226-1:2008 (aqueous extract)	identical
Paper or Paperboard, with a mass ≤ 400 g/m²	30 mg/kg (content)	EN 645:1993 and EN 1541:2001 (aqueous extract)	identical But: No definition for paper in Annex C
Accessible liquids, Modelling clay, Tattoos	500 mg/kg (content)	Directive 90/207/EEC (free formaldehyde by post-column derivatization)	different test method; higher limit value; EN 71-9 also considers materials for children > 3 years!

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