TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products – Information

February 2021

Adaptation of the Toy Safety Directive 2009/48/EC
New Admission of Formaldehyde in Annex II Appendix C

Present legal Regulation for Formaldehyde in Toys

Formaldehyde [CAS-No. 50-00-0] is classified as carcinogenic Category 1B according to CLP Regulation (EC) No. 1272/2008; the generic concentration limit applies. Therefore, the **general ban on CMR substances** as settled Annex II part III No. 3 of the **Toy Safety Directive** comes into force and the concentration of formaldehyde in accessible materials of toys shall be **below 0.1 % (1000 mg/kg)**.

In addition, there are further requirements concerning formaldehyde in **EN 71 part 9**. Those specifications are similar to the new requirements in Appendix C, which are valid from 21 May 2021. However, there are differences in the application scope, limit value and/or test method.
Although EN 71 part 9 is not referenced (harmonised) in the EU Official Journal and therefore not binding for a presumption of conformity with the Toy Safety Directive, it has been implemented as a safety-relevant standard in most EU states by a national legal requirement. Therefore, authorities check these specifications frequently.

In addition, in Germany an emission limit value for Formaldehyde is laid down in the national ordinance on the prohibition of chemicals “Chemikalienverbotsverordnung“ (ChemVerbotsV). However, this requirement applies only to wood-based materials that are placed on the market as material (chipboard, blockboard, veneer panels, and fibreboard, etc.) and furniture as a finished product. Thus, the prohibitions affects toys only if they are craft sets with wooden materials or a product with a dual function as a piece of furniture.

Future Requirements for Toy Materials acc. to Appendix C

Directive 2019/1929/EU of the Commission dated 19 November 2019:

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 extraction)
leather	30 mg/kg (content)	EN ISO 17226-1:2019 (aqueous extraction)
paper material	30 mg/kg (content)	EN 645:1993 und EN 1541:2001 (aqueous extraction)
water-based material	10 mg/kg (content)	EDQM (free formaldehyde in cosmetics)

*corresponds to wood-based materials of **formaldehyde emission class E1** as defined in the harmonized European standard EN 13986 for wood-based materials for use in construction

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431 Nürnberg
Phone.: +49 911 655 5225 • Fax: +49 911 655 5226
E-Mail: service@de.tuv.com • www.tuv.com

Board of Management
Dipl.-Ing. Jörg Mähler (Spokesman), Dipl.-Kfm. Dr. Jörg Schlösser
Registered office and court of registry Nuremberg HRB 26013
VAT No. DE811835490

Dated of: 10.02.2021, printed on: 10.02.2021

Appendix C applies to toys intended for use by children under 36 months or in other toys intended to be placed in the mouth.

The new specifications will come into effect on **21 May 2021**.

In the following, the requirements for the individual materials are examined in more detail and, in particular, the differences to EN 71-9 as well as to the German ordinance on the prohibition of chemicals are be described. In the tables, significant differences are shown in **bold**; the stricter requirement is marked in red in each case.

1) Polymers (e.g. Formaldehyde resins)

After new toxicological evaluation, a formaldehyde migration limit of 1.5 mg/l has defined. This is **below the migration limit of EN 71-9** and means a **tightening** of the previous requirements.

In addition, Appendix C covers all materials in toys for children under 3 years of age, whereas EN 71-9 covers only toy materials children will foreseeably put in the mouth.

a) Toy for children under 3 years of age that *is intended* to be put in the mouth.

b) Toys or accessible toy components with a mass of ≤ *150 g*, which are intended for children under 3 years of age for playing with their hands.

Thus, the scope of Appendix C extends to additional materials such as the body of a ride-on vehicle or bouncy balls. **This will lead to a higher scope of testing in the future!**

EN 71-10:2005 + EN 71-11:2005 shall be used as the test method in each case. **If a material falls within the scope of both specifications, double testing of the monomers is not necessary.**

	Appendix C	**EN 71-9**
Limit value	1.5 mg/l (migration)	2.5 mg/l (migration)
Test method	EN 71-10:2005 + EN 71-11:2005 (aqueous migrate)	EN 71-10:2005 + EN 71-11:2005 (aqueous migrate)
Scope	• toys for children < 3 years: **all materials** • materials intended to be put in the mouth	• toy for children < 3 years: materials foreseeably put in the mouth • materials intended to be put in the mouth • toys worn over the mouth or nose • graphic instruments • toys which mimic food • imitation jewellry

2) Wood-based Materials

The ban applies exclusively to resin-bonded wood products [particle board, oriented-strand board (OSB), high-density fibre board (HDF), medium density fibre board (MDF) and plywood]. **Solid wood and products made of glued solid wood are not mentioned.**

	Appendix C	**EN 71-9**	**ChemVerbotsV**
Limit value	0.1 ml/m³ (emission)	80 mg/kg dry wood	0.1 ml/m³ (emission)**
Test method	EN 717-1:2004 (test chamber)	EN 717-3 (WKI flask method)	DIN EN 16516 EN 717-1:2004 (test chamber)
Scope	• toys for children < 3 years: **all materials** • materials intended to be put in the mouth	• toys for children < 3 years: **accessible components**	• wood-based materials that are placed on the market as such • furniture

**significant tightening of requirements by stricter test conditions (EN 16516) or due to the consideration of the doubling of the measured value required for the evaluation (EN 717-1:2004)

Due to the **lack of correlation** of the measurement results from both test methods - **EN 717-1** versus **EN 717-3**, a **separate test** of the wood-based materials according to EN 717-1 is required for the proof of conformity with Appendix C.

Wood-based materials that meet the requirements of the German ordinance on the prohibition of chemicals or the requirements for emission class E1 are also suitable for use in toys!

The implementation of the new formaldehyde emission requirements according to Appendix C leads to an **extension of the required scope of testing** for toys and, as a consequence, to **additional testing costs**. Furthermore, **testing capacities** must be kept free in the central laboratory.

Current status of Directive Implementation in Germany

At present, there has been no coordinated approach of the authorities or the expert committee for the GS-Mark (AK 2.6), yet. We do not have any information on current actions of other EU states.

Nevertheless, we can offer our customers a useful service to confirm conformity. As long as no harmonized approach is defined, an assessment according to the following internal review scenario is proposed:

As a **main procedure**, the conformity with the directive is checked by means of a **whole body test** according to EN 717-1. If an overall product complies with the applicable requirement, it is considered to comply with the essential requirements (for materials/wood-based materials).

Alternatively, compliance with the requirements can be ensured by testing wood-based materials **delivered separately.**

Requirements for an internal Implementation:

The surfaces of wooden materials used in toys are often insufficiently large to be tested according to the specifications of EN 717-1. If necessary, a high number of individual items have to be provided for testing. This can be significantly reduced by switching to test chambers with a smaller volume (desiccator).

The **timely provision of reliable information** on the wood-based materials used helps to avoid excessive **testing depth** and thus reduce **costs** as well as the strain on **testing capacities**.
The following data are required for this:

- Type of wood-based materials (MDF, plywood, etc.)
- Type of coating (lacquered, plastic-coating, uncoated etc.)
- Thickness of materials (in mm).

An additional indication of size of the surfaces of the materials in a toy article enables testing according to a **worst-case scenario**.

3) Textiles

Appendix C has defined a broader scope compared to EN 71-9.

	Appendix C	**EN 71-9**
Limit value	30 mg/kg	30 mg/kg
Test method	EN ISO 14184-1:2011 (aqueous extraction)	EN ISO 14184-1:2011 (aqueous extraction)
Scope	• Toys for children < 3 years: **all materials** • materials intended to be put in the mouth	• accessible toy components for children under 3 years

However, this will hardly be of any significance for practice. Experience has shown that textiles that are put in the mouth do not play a role in toys. For inaccessible textiles, finishing with formaldehyde is rather irrelevant. An increasing number of required examinations is not to be expected here.

4) Leather

Requirements differ completely. Appendix C considers Formaldehyde above all as tanning and finishing agent. Whereas EN 71-9 considers Formaldehyde as a preservative. This results in different test methods and limit values.

	Appendix C	**EN 71-9**
Limit value	30 mg/kg	500 mg/kg
Test method	**EN ISO 17226-1:2019** (**extraction** with detergent solution; **total** formaldehyde)	EN 71-10 + DIR 90/207/EWG (aqueous migrate; free formaldehyde by post-column derivatisation)
Scope	• Toys for children < 3 years: **all materials** • materials intended to be put in the mouth	• accessible toy components for children under 3 years

For cost reasons, real leather is extremely rarely used in toys. However, should it occur, **both requirements must be checked separately.**

5) Paper

Limit value and test method are identical, however, Appendix C includes all paper materials regardless of the basis weight and is valid for all toy articles regardless of their total weight.

	Appendix C	**EN 71-9**
Limit value	30 mg/kg	30 mg/kg
Test method	EN 645:1993 and EN 1541:2001 (aqueous extraction)	EN 645:1993 and EN 1541:2001 (aqueous extraction)
Scope	Paper and cardboard in general • Toys for children < 3 years: **all materials** • materials intended to be put in the mouth	Paper or cardboard with a **basis weight ≤ 400 g/m²** • toys or accessible toy components with a **weight ≤ 150 g**, intended for children under 3 years of age for playing with their hands • mouth-piece parts of mouth-operated toys • Toys worn over the mouth or nose

6) Water-based Materials (Formaldehyde as a preservative.)

Due to the carcinogenic properties of formaldehyde, the lowest reliably determinable value has been laid down as the limit value in Appendix C. A **new test method** for cosmetics is used for the determination.
Whereas EN 71-9 refers to an older test method and contains a **higher limit value**. However, in addition the standard EN 71-9 covers liquids in toys for children from 3 years and all modelling clays.

	Appendix C	**EN 71-9**
Limit value	10 mg/kg	500 mg/kg
Test method	EDQM (free Formaldehyde by short term-short derivatization)	EN 71-10 + DIR 90/207/EWG (free formaldehyde by post-column derivatisation)
Scope	• Toys for children < 3 years: all materials • materials intended to be put in the mouth	All toys (**also > 3 years**): • accessible liquids in toys • modelling clay, play dough and similar material • removable (fake) tattoos with glue

Both test methods shall determine „free formaldehyde“. However, they differ significantly in derivatisation and thus the measured values are not comparable. It is not possible to estimate which test method provides a higher result. (a.o. depending on the sample matrix and the used preservative). **Therefore, conformity acc. to Appendix C and EN 71-9 must be confirmed by separate tests.**

Comparison to current Requirements of the Criteria Catalogue 2 PfG S 0160 dated 01.2019

- Monomers in polymers: The criteria catalogue does not contain specific requirements.
- Resin-bonded wood: The criteria catalogue merely reproduces the existing legal requirements of the German ordinance on the prohibition of chemicals with its original scope of application (craft sets as well as articles with dual function as furniture).
- Textiles and leather: The criteria catalogue covers the new requirements. *There is no additional need for action for certificate holders.*
- Paper and cardboard: The criteria catalogue covers the new requirements. *There is no additional need for action for certificate holders.*
- Water-based mixtures: The criteria catalogue is oriented only towards the existing requirements with regard to Formaldehyde as a preservative (EN 71-9). Appendix C has not been considered, yet.

For further technical information please contact:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
D-90431 Nürnberg

Technical Competence Center Toys
Dr. Kathrin Birkmann
Phone +49 911/655-5863
Kathrin.Birkmann@de.tuv.com

Technical Competence Center VOC Emissions & Test Chamber Examinations
Dr. Jelena Galinkina
Phone +49 911/655-5614
Jelena.Galinkina@de.tuv.com