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Safety of toys - Part 9: Organic chemical compounds - Requirements

Sicherheit von Spielzeug - Teil 9: Organisch-chemische Verbindungen - Anforderungen

Sécurité des jouets - Partie 9 : Composés organiques chimiques - Exigences

Ta slovenski standard je istoveten z: **EN 71-9:2005**

[SIST EN 71-9:2005](https://standards.iteh.ai/catalog/standards/sist/1acf030d-4c6b-4942-ace2-362d333bd083/sist-en-71-9-2005)

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**ICS:**

97.200.50 Q|æ^

Toys

**SIST EN 71-9:2005**

**en,fr,de**

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ICS 97.200.50

English version

## Safety of toys - Part 9: Organic chemical compounds - Requirements

Sécurité des jouets - Partie 9: Composés chimiques  
organiques - Exigences

Sicherheit von Spielzeug - Teil 9: Organisch-chemische  
Verbindungen - Anforderungen

This European Standard was approved by CEN on 15 November 2004.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

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## Foreword

This document (EN 71-9:2005) has been prepared by Technical Committee CEN/TC 52 "Safety of Toys", the secretariat of which is held by DS.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2005, and conflicting national standards shall be withdrawn at the latest by August 2005.

This standard constitutes part 9 of the European Standard on Safety of Toys.

This part should be read in conjunction with parts 10 and 11.

This document defines contact routes and specifies limits for the migration or content of certain chemical compounds in toys.

This document contains three annexes:

- Annex A (informative) Rationale
- Annex B (informative) Conformity assessment
- Annex ZA (informative) Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

## Introduction

The document EN 71 for safety of toys consists of the following parts.

- Part 1: *Mechanical and physical properties*
- Part 2: *Flammability*
- Part 3: *Migration of certain elements*
- Part 4: *Experimental sets for chemistry and related activities*
- Part 5: *Chemical toys (sets) other than experimental sets*
- Part 6: *Graphical symbols for age warning labelling*
- Part 7: *Finger paints – Requirements and test methods*
- Part 8: *Swings, slides and similar activity toys for indoor and outdoor family domestic use*
- Part 9: *Organic chemical compounds – Requirements*
- Part 10: *Organic chemical compounds – Sample preparation and extraction*
- Part 11: *Organic chemical compounds – Methods of analysis*

The documents EN 71-9, prEN 71-10 and prEN 71-11 were mandated by the European Commission (M/229) to address the risks presented by organic compounds in toys by taking into account the potential exposure and toxicological effects of those substances considered to present the greatest risk to health.

This document gives requirements for organic compounds in certain toys and toy materials. In drafting the document, CEN/TC 52 considered the risks associated with more than 650 organic compounds. It was recognized that not all potentially hazardous organic compounds could be addressed. The Commission further restricted the Mandate to substances classified as dangerous under Council Directive 67/548/EEC. This document, therefore, supports but does not reduce the responsibility of toy manufacturers, importers and suppliers for ensuring that the use of other substances will not endanger the health whilst playing with toys as intended or in a reasonably foreseeable way. In addition, there should be no exposure to children from toys, in amounts which may harm their health, of organic chemical substances which are classified by other relevant statutes as carcinogenic, mutagenic or toxic for reproduction and for which no requirements are specified in this document.

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Future editions of this document will address additional organic compounds. It might be useful for manufacturers of toys to consider the risk assessments carried out during the drafting of this document and published as part of a CEN report which supports the standard. Users of this document are reminded that compliance with the standard can only provide presumption of conformity with the essential safety requirements of the Toys Safety Directive in respect of the substances addressed.

This part should be read in conjunction with prEN 71-10, which describes sample preparation and extraction procedures, and prEN 71-11, which specifies methods of analysis.

At the date of publication, the standard does not specify requirements for chemical compounds which are prohibited in toys by Council Directive 76/769/EEC of 27<sup>th</sup> July 1976, as amended, on restrictions on the marketing and use of certain dangerous substances and preparations.

This document takes into account the opinion of the Toxicology Section of the Scientific Advisory Committee published in 1992 (EUR 13976) which recommended that certain groups of chemical compounds used in toys and toy materials need to be given special attention. In drafting this document CEN/TC 52 has considered organic chemicals that can be classified within the following groups:

- Solvents
- Preservatives
- Plasticisers (excluding phthalate plasticisers)<sup>1</sup>
- Flame retardants
- Monomers

<sup>1</sup> Phthalate plasticisers were specifically excluded from the scope of mandate M/229.

- Biocides (wood preservatives)
- Processing aids
- Colouring agents

During the development of this document, CEN/TC 52 has considered the requirements set out in Council Directive 82/711/EEC as amended and its supporting standards.

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## 1 Scope

This Part 9 of the document EN 71 for safety of toys specifies requirements for the migration or content of certain hazardous organic chemical compounds from/in certain toys and toy materials (see Table 1) by the following exposure routes:

- mouthing
- ingestion
- skin contact
- eye contact
- inhalation

when used as intended or in a foreseeable way, bearing in mind the normal behaviour of children and the function and design of the toy.

This document does not contain requirements for chemical toys, experimental sets or finger-paints, which are addressed by other parts of EN 71.

Packaging materials used with toys are not within the scope of the document unless they form part of the toy or have intended play value.

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 71-1:1998, *Safety of toys - Part 1: Mechanical and physical properties*  
SIST EN 71-9:2005  
<https://standards.iteh.ai/catalog/standards/sist/1ac1056d-4c6b-4942-acc2-362d333bd083/sist-en-71-9-2005>

EN 71-5, *Safety of toys – Part 5: Chemical toys (sets) other than experimental sets*

prEN 71-10:, *Safety of toys – Organic chemical compounds – Sample preparation and extraction*

prEN 71-11, *Safety of toys – Organic chemical compounds – Methods of analysis*

EN 645, *Paper and board intended to come into contact with foodstuffs – Preparation of a cold water extract*

EN 717-3, *Wood-based panels – Determination of formaldehyde release – Part 3: Formaldehyde release by the flask method*

EN 1541, *Paper and board intended to come into contact with foodstuffs - Determination of formaldehyde in an aqueous extract*

EN ISO 787-9, *General methods of test for pigments and extenders – Part 9: Determination of pH value of aqueous suspension (ISO 787-9:1981)*

EN ISO 14184-1, *Textiles – Determination of formaldehyde – Part 1: Free and hydrolysed formaldehyde (water extraction method) (ISO 14184-1:1998)*

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.



**3.1****accessible**

contact with the articulated probe when tested in accordance with the 'accessibility-of-a-part-or-component' test in EN 71-1

**3.2 (see A.2)****accessible liquid**

liquid in or on a toy or accompanying a toy to which the child is likely to become exposed during normal or foreseeable use of the toy (e.g. liquid paints, bubble liquids, ink in pens, liquids provided with toys for squirting)

**3.3****mouth-actuated toy**

toy which relies on an action of the mouth to operate and which therefore is designed to come into contact with the mouth during play (e.g. toy whistles, toy imitation novelty teeth). Inflatable toys are not considered mouth-actuated toys unless they rely on an action of the mouth after inflation

**3.4****mouthed**

licked, sucked and chewed

**3.5****paper**

material, marketed as either paper or paperboard, with a maximum mass per unit area of 400 g/m<sup>2</sup> [EN 71-1:1998]

**3.6 (see A.3)****polymeric**

consisting of plastic, synthetic rubber, natural rubber, silicone polymer but not other natural polymers

**3.7****resin-bonded wood**

wood-based material, for example, plywood, particle board, chipboard and medium-density fibreboard (MDF)

**3.8****textile**

woven or knitted fabrics, non-woven fibrous material (e.g. felt)

**3.9****toy material**

material from which toys and toy components are made

**3.10****toy which a child can enter**

any toy, having a door, lid or similar device, which encloses a continuous volume greater than 0.03 m<sup>3</sup> and in which all internal dimensions are 150 mm or more.

**4 Requirements****4.1 Limits (see A.4)**

**4.1.1** Table 1 specifies toys, toy components and *toy materials* for which this document contains requirements. An "X" is indicated in columns 2A – 2I when requirements are given in the limit Tables 2 A – 2 I for certain groups of organic chemicals. The toys and *accessible* toy components specified in Table 1 shall not contain or release the organic compounds in the relevant limit tables in amounts which exceed the limits specified.

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**4.1.2** If a limit specified in a limit table is expressed as “Action limit”, the relevant limit shall be the limit of the applicable method as specified in prEN 71-11.

NOTE See also **4.4** relating to methods of analysis.

**4.1.3** If a particular toy or toy component fits more than one of the descriptions given in Table 1, then the limit tables indicated for each of the descriptions shall apply to that toy or *accessible* toy component.

### 4.2 Liquids in toys (see A.5)

**4.2.1** Toys shall not contain *accessible liquids* classified in accordance with Directive 1999/45/EC as very toxic, toxic, harmful, corrosive, irritant or sensitising; and the *accessible liquids* shall not contain substances that are classified as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2. However, as a derogation, liquids present as ink supplied in writing instruments may be classified ‘R36 Irritating to eyes’.

**4.2.2** *Accessible liquids* in toys shall not have a pH of less than 3,0 or greater than 10,0 when tested in accordance with EN ISO 787-9. This requirement does not apply to ink supplied in writing instruments.

**4.2.3** Toys shall not contain liquids classified in accordance with Directive 1999/45/EC as R65 ‘Harmful: may cause lung damage if swallowed’.

### 4.3 Formaldehyde (see A.6)

**4.3.1** *Accessible textile* components of toys intended for children under 3 years of age shall not contain free and hydrolyzed formaldehyde in excess of 30 mg/kg when tested in accordance with EN ISO 14184-1.

**4.3.2** *Accessible paper* components of toys intended for children under 3 years of age shall not contain formaldehyde in excess of 30 mg/kg when tested in accordance with EN 645 and EN 1541.

**4.3.3** *Accessible resin-bonded wood* components of toys intended for children under 3 years of age shall not release formaldehyde in excess of 80 mg/kg when tested in accordance with EN 717-3.

NOTE This document also contains requirements for formaldehyde as a monomer (see Table 2 D) and as a preservative (see Table 2 H).

### 4.4 Methods of analysis (see A.7)

The analysis of toys and *toy materials* for chemical compounds for which limits are given in Tables 2 A to 2 I shall be performed in accordance with the sampling procedures and test methods described in prEN 71-10 and prEN 71-11. Alternative methods are acceptable only if they are capable of achieving at least the accuracy, precision and sensitivity of the standard methods and have been validated to show that the results are equivalent to those of the standard methods.

If a first-action method is given in prEN 71-10 for a particular toy, toy component and *toy material* and compound or group of compounds, compliance with this document may be shown by using that method alone. A first-action method shall not be used to show non-compliance with the requirements of this document.

Table 1 – Applicable limit Tables (4.1) (see A.8 and A.9)

	SPECIFIC TOY/TOY COMPONENT	Toy material	Limit table									
			2 A	2 B	2 C	2 D	2 E	2 F	2 G(a)	2 G(b)	2 H	2 I
			Flame retardants	Colourants	Primary aromatic amines	Monomers	Solvents - migration	Solvents - inhalation	Wood preservatives	Wood preservatives	Preservatives	Plastics
1	Toys intended to be <i>mouthed</i> by children under 3 years of age	POLYMERIC <sup>a</sup>				X	X					X
2	Toys, or <i>accessible</i> toy components, with a mass of 150 g or less intended to be played with in the hands by children under 3 years of age	POLYMERIC <sup>a</sup>				X	X					X
3		WOOD		X	X				X	X		
4		PAPER		X	X							
5	Toys and <i>accessible</i> components of toys intended for children under 3 years of age	TEXTILE	X	X	X							
6		LEATHER		X	X						X	
7	Mouthpiece components of <i>mouth-actuated</i> toys	POLYMERIC <sup>a</sup>				X	X					X
8		WOOD		X	X				X	X		
9		PAPER		X	X							
10	Inflatable toys with a surface greater than 0,5 m <sup>2</sup> when fully inflated	POLYMERIC <sup>a</sup>						X				
11	Toys worn over the mouth or nose	POLYMERIC <sup>a</sup>				X		X				
12		TEXTILE		X	X			X				
13		PAPER		X	X							
14	Toys which the child can enter	POLYMERIC <sup>a</sup>						X				
15		TEXTILE						X				
16	Components of graphic instruments sold as toys or used in toys	POLYMERIC <sup>a</sup>				X	X					X
17	Toys and <i>accessible</i> components of toys for indoor use	WOOD							X	X		
18	Toys and <i>accessible</i> components of toys for outdoor use	WOOD							X			
19	Toys and components of toys which mimic food	POLYMERIC <sup>a</sup>				X	X					X
20	Solid toy materials intended to leave a trace	ALL		X	X							
21	Coloured <i>accessible liquids</i> in toys	LIQUID		X	X						X	
22	Non-coloured <i>accessible liquids</i> in toys	LIQUID									X	
23	Modelling clay, play clay and similar, except those chemical toys addressed by EN 71-5	ALL		X	X						X	
24	Balloon-making compounds	ALL		X	X			X				
25	Imitation tattoos with adhesive	ALL		X	X		X				X	
26	Imitation jewellery	POLYMERIC <sup>a</sup>				X	X					X

<sup>a</sup> excluding polymeric coatings with a thickness of less than 500 µm.

NOTE If a limit table is not indicated in this table for a toy, toy component and *toy material*, then that limit table is not intended to be applied to that particular toy, toy component and *toy material*. The limits given in the limit tables have been calculated with the specific toy and toy material in mind. In the case of other toys and toy materials not specified, they may not be appropriate and should not be applied without further expert toxicological/exposure assessment.