



SLOVENSKI STANDARD
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Izdelki za otroke - Kemijske nevarnosti - Zahteve in preskusne metode

Child care articles - Chemical hazards - Requirements and test methods

Artikel für Säuglinge und Kleinkinder - Chemische Gefährdungen - Anforderungen und Prüfverfahren

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Child care articles - Chemical hazards - Requirements and test methods

Artikel für Säuglinge und Kleinkinder - Chemische Gefährdungen - Anforderungen und Prüfverfahren

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 252.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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 CEN-CENELEC Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (prEN 17826:2022) has been prepared by Technical Committee CEN/TC 252 “Child care articles”, the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN Enquiry.

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

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

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prEN 17826:2022 (E)**1 Scope**

This document specifies chemical requirements, test and compliance assessment methods for child care articles within the scope of CEN TC 252.

Excluded from the scope are soothers (EN 1400), soother holders (EN 12586), drinking equipment, (EN 14350) and cutlery and feeding utensils (EN 14372).

NOTE A non-exhaustive list of standards for child care articles covered by TC 252 is given in Annex A. An up-to-date list can be found on the CEN website: <https://standards.cen.eu/dyn/www/f?p=204:105:0>

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 71-3:2019+A1:2021, *Safety of toys - Part 3: Migration of certain elements*

EN 71-10:2005, *Safety of toys - Part 10: Organic chemical compounds - Sample preparation and extraction*

EN 71-11:2005, *Safety of toys - Part 11: Organic chemical compounds - Methods of analysis*

EN 717-1:2004, *Wood-based panels - Determination of formaldehyde release - Part 1: Formaldehyde emission by the chamber method*

EN ISO 14184-1:2011, *Textiles - Determination of formaldehyde - Part 1: Free and hydrolysed formaldehyde (water extraction method) (ISO 14184-1:2011)*

EN ISO 14362-1:2017, *Textiles - Methods for determination of certain aromatic amines derived from azo colorants - Part 1: Detection of the use of certain azo colorants accessible with and without extracting the fibres (ISO 14362-1:2017)*

EN ISO 17226-1:2021, *Leather - Chemical determination of formaldehyde content - Part 1: Method using high-performance liquid chromatography (ISO 17226-1:2021)*

EN ISO 17234-1:2020, *Leather - Chemical tests for the determination of certain azo colourants in dyed leathers - Part 1: Determination of certain aromatic amines derived from azo colorants (ISO 17234-1:2020)*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

article

object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition

[SOURCE: REACH, Article 3.3]

3.2

child care article

article used by small children in the scope of CEN TC 252

4 Requirements

4.1 General chemical requirements

This standard supports but does not reduce the responsibility of manufacturers, importers and suppliers for ensuring that the use of substances not addressed will not endanger the health whilst using child care articles as intended or in a reasonably foreseeable way.

Parts of the product which shall comply with this standard are defined in the relevant product safety standards based on their accessibility, function, volume or mass, and reasonable exposure due to sucking, licking, swallowing, inhalation or prolonged contact with skin.

NOTE 1 'Prolonged contact with human skin' has been defined in REACH in different ways for different substances. In the REACH restriction on phthalates (2018/2005) it means continuous contact of more than 10 min duration or intermittent contact over a period of 30 min, per day. In the ECHA Guide relating to the nickel restriction it means 10 min on three or more occasions within two weeks, or 30 min on one or more occasions within two weeks. For other substances other definitions may be appropriate.

When these parts of the product are not defined in the relevant product safety standards, the parts of the products which shall comply shall be defined using the exposure principles described in this standard.

Requirements for substances on the "Candidate list" (4.3) apply to any part of any child care article.

Requirements relating to emissions of volatile organic compounds (solvents (inhalation), fragrances, release of formaldehyde from resin-bonded wood panels) apply to any part of any child care article specified in the relevant clause of this standard if exposure cannot be excluded.

NOTE 2 Future editions of this standard may incorporate additional requirements addressing exposure to such as adults or children other than these using the product.

prEN 17826:2022 (E)**4.2 Compliance assessment for requirements**

Typically, normative requirements in standards are verified using incorporated or referenced test methods. However, this approach has its limitations. The application of test methods is expensive and, in many cases, difficult if not impossible. As an example, generic restrictions of substances classified as CMR cover potentially hundreds of compounds. It would be extremely difficult to develop, to validate or to identify appropriate test methods for all of them. But even where such methods are available it may be more useful and more efficient to assess compliance with the provisions of this standard in a different way through an evaluation of the technical documentation associated with the product and the materials/chemicals used for its production.

The starting point for a compliance assessment is the gathering of information on the materials and chemicals used in the manufacture of the child care article. A comprehensive information in the form of a bill of materials (BOM), a bill of substances (BOS) and in support of these, safety data sheets (SDS), regulatory declarations by materials manufacturers, certificates, test reports, where applicable, shall be compiled. A description of the use/location of the material shall be given in a way that makes it possible to assess whether the provisions of the standard are fulfilled, e.g. to determine whether a part can reasonably be expected to lead to an exposure due to sucking, licking, swallowing, inhalation or prolonged contact with skin.

The harmonized hazard classification of substances present in the final product shall be determined e.g. by using the relevant databases operated by ECHA.

NOTE 1 Harmonized hazard classifications of substances are included in Part 3 of Annex VI of the Regulation on classification, labelling and packaging of substances and mixtures (Regulation EC/1272/2008, "CLP-Regulation").

Finally, it shall be determined whether substances restricted in this standard are present in parts specified in the relevant clauses in amounts exceeding the relevant thresholds where it is indicated that compliance assessment may be used instead of testing.

Unless explicitly stated in this standard testing is not required, however, additional (supporting) testing may be useful for managing compliance. The implementation of a Quality Management System (QMS) with appropriate considerations for managing chemicals and chemical risks throughout the value chain may also assist in compliance assessment. These additional compliance assessment options are described in Annex B (informative).

NOTE 2 The above procedure was inspired by the "Guidance document on the application of Directive 2009/48/EC on the Safety of toys: Technical documentation, specifically Part IV Chemical Requirements.

4.3 Substances on the "Candidate list"

Substances included in the Candidate list (including substances in Annex XIV) of REACH shall not exceed 0,1 % in components of child care articles 18 months after publication on the Candidate list.

Components which are not accessible without using tools are not covered by the requirement.

Where more specific limits for substances on the Candidate list are stipulated in this standard such limits prevail over the generic ones.

Evaluation of this clause shall be done in accordance with 4.2.

4.4 CMR substances

Substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be present in any part which, due to their accessibility, function, volume or mass, can reasonably lead to an exposure due to sucking, licking, swallowing, inhalation or prolonged contact with skin if exceeding the following limits:

- for carcinogenic and mutagenic substances 0,1 %, 0,1 % and 1 % (for cat. 1A, 1B and 2);
- for substances toxic to reproduction 0,3 %, 0,3 % and 3 % (for cat. 1A, 1B and 2);
- in accordance with the specific limits included in Annex VI, Table 3.1 of Part 3 of Regulation (EC) No 1272/2008.

This requirement does not apply to nickel in child care articles and child care article components made of stainless steel.

NOTE It is envisaged to incorporate future exemptions included in Appendix A of the TSD in amendments to this standard.

Where more specific limits for CMR substances are stipulated in this standard such limits prevail over the generic ones.

Evaluation of this clause shall be done in accordance with Clause 4.2.

4.5 Certain elements

The migration of elements from any parts which, due to their accessibility, function, volume or mass, can reasonably lead to an exposure due to sucking, licking, swallowing, or prolonged contact with skin shall not exceed any of the limits given in Table 1.

The method described in EN 71-3:2019+A1:2021 shall be used.

<https://standards.iteh.ai/catalog/standards/sist/4d633650-044a-4c30-b484-aca81c07b4c6/osist-pren-17826-2022>

Table 1 — Migration limits of certain elements

Element	mg/kg
Aluminium	28 130
Antimony	560
Arsenic	47
Barium	18 750
Boron	15 000
Cadmium	17
Chromium (III)	460
Chromium (VI)	0,053
Cobalt	130
Copper	7 700
Lead	23
Manganese	15 000
Mercury	94
Nickel	930
Selenium	460
Strontium	56 000
Tin	180 000
Organic tin	12
Zinc	46 000

4.6 Flame retardants

[oSIST prEN 17826:2022](https://standards.iteh.ai/catalog/standards/sist/4d633650-1044-4211-81ac0-0d1316608181/prEN17826:2022)

Materials made of plastics, foams, textiles and wood shall not contain any substances typically used as flame-retardants (but may be used for other purposes) exceeding the limits given in Table 2.

For the listed flame retardants with a limit value, methods shall be used with a suitable limit of quantitation (LOQ) allowing to verify the indicated limits.

Table 2 — Flame retardant limits

Compound	CAS Number	Limit
Tri-o-cresyl phosphate (TOCP)	78-30-8	see clause plasticizer
Tris(2-chloroethyl) phosphate (TCEP)	115-96-8	5 mg/kg
Tris(1,3-dichloropropyl-2) phosphate (TDCPP)	13674-87-8	5 mg/kg
Tris-monochloro-propyl phosphate (TCPP)	13674-84-5	5 mg/kg
Triphenyl phosphate (TPP)	115-86-6	see clause plasticizer

4.7 Colorants

Colourants given in Table 3 shall not be used in parts made of textiles and leather which, due to their accessibility, function, volume or mass, can reasonably lead to an exposure due to sucking, licking, swallowing, or prolonged contact with skin.

The absence of the listed colourants shall be evaluated in accordance with 4.2.

Table 3 — Restricted colourants

Colour Index Generic Name (CIGN)	Colour Index Constitution Number (CICN)	CAS Number
Acid Red 26	16150	3761-53-3
Acid Red 114	23635	6459-94-5
Acid Violet 49	42640	1694-09-3
Basic Blue 26 (with $\geq 0,1\%$ Michler's ketone) or base)	44045	2580-56-5
Basic Green 4	42000	68513-86-0, 569-64-2, 2437-29-8, 10309-95-2
Basic Red 9	42500	569-61-9
Basic Violet 1	42535	8004-87-3
Basic Violet 3	42555	548-62-9
Basic Violet 3 (with $\geq 0,1\%$ Michler's ketone) or base)	42555	548-62-9
Basic Violet 14	42510	632-99-5
Direct Black 38	30235	1937-37-7
Direct Blue 3	23705	2475-46-9
Direct Blue 6	22610	2602-46-2
Direct Blue 15	24400	2429-74-5
Direct Brown 95	30145	16071-86-6
Direct Red 28	22120	573-58-0
Disperse Blue 1	64500	2475-45-8
Disperse Blue 3	61505	2475-46-9
Disperse Blue 7	62500	3179-90-6
Disperse Blue 26	63305	3860-63-7
Disperse Blue 35		12222-75-2
Disperse Blue 102	111945	12222-97-8
Disperse Blue 106	111935	12223-01-7
Disperse Blue 124	111938	61951-51-7
Disperse Brown 1	11152	23355-64-8
Disperse Orange 1	11080	2581-69-3
Disperse Orange 3	11855	730-40-5