

English Version

Child care articles - General safety guidelines - Part 2: Chemical hazards

Articles de puériculture - Conseils relatifs à la sécurité -
Partie 2 : Dangers chimiques

Artikel für Säuglinge und Kleinkinder -
Sicherheitsleitfaden - Teil 2: Chemische Gefährdungen

This Technical Report was approved by CEN on 16 March 2018. It has been drawn up by the Technical Committee CEN/TC 252.

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



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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents	Page
European foreword.....	5
1 Scope	6
2 Normative references	6
3 Terms and definitions	6
4 Regulatory, normative and policy background	6
4.1 General.....	6
4.2 REACH - Short summary	7
4.2.1 Registration.....	7
4.2.2 Authorization.....	7
4.2.3 Restrictions	7
4.2.4 Articles	7
4.2.5 Recommendations	8
4.3 Toy Safety Directive and related standards	8
4.3.1 Short summary of Toy Safety Directive.....	8
4.3.2 Toy standards.....	9
4.3.3 Recommendations	10
4.4 CEN Approach on addressing environmental issues in product and service standards....	11
4.4.1 Short summary.....	11
4.4.2 Recommendations	11
5 Basics of Chemical Safety Assessment (CSA)	11
5.1 General.....	11
5.2 Hazard assessment.....	12
5.3 Exposure assessment.....	14
5.4 Risk characterization.....	14
5.5 Example – PAHs.....	15
5.6 Example – Migration limit values in Toy Safety Directive.....	15
5.7 Recommendations	16
6 Child care articles specific approaches	16
6.1 General aspects.....	16
6.2 Substances of Very High Concern (SVHC)	17
6.3 CMR substances	17
6.4 Certain elements	17
6.4.1 Regulatory and normative background	17
6.4.2 Specific child care articles considerations.....	18
6.5 Flame retardants.....	18
6.5.1 Regulatory and normative background.....	18
6.5.2 Specific child care articles considerations.....	19
6.6 Colourants.....	19
6.6.1 Regulatory and normative background.....	19
6.6.2 Specific child care articles considerations.....	20
6.7 Primary aromatic amines	21
6.7.1 Regulatory and normative background.....	21
6.7.2 Specific child care articles considerations.....	21
6.8 Monomers.....	22
6.8.1 Regulatory and normative background.....	22

6.8.2	Specific child care articles considerations	22
6.9	Solvents (migration).....	22
6.9.1	Regulatory and normative background	22
6.9.2	Specific child care articles considerations	23
6.10	Solvents (inhalation)	23
6.10.1	Regulatory and normative background	23
6.10.2	Specific child care articles considerations	24
6.11	Plasticizers	24
6.11.1	Regulatory and normative background	24
6.11.2	Specific child care articles considerations	25
6.12	Sensitizers – Fragrances.....	25
6.12.1	Regulatory and normative background	25
6.12.2	Specific child care articles considerations	28
6.13	N-Nitrosamines and N-Nitrosatable substances.....	28
6.13.1	Regulatory and normative background	28
6.13.2	Specific child care articles considerations	28
6.14	Other – Formaldehyde (other than monomer or preservative)	29
6.14.1	Regulatory and normative background	29
6.14.2	Specific child care articles considerations	29
A.1	Organostannic compounds	30
A.2	Cadmium	30
A.3	Nickel.....	30
A.4	Chromium VI.....	30
A.5	Lead	31
A.6	Flame retardants	31
A.7	Colourants	31
A.8	Wood preservatives.....	31
A.9	Preservatives (other than wood preservatives)	32
A.10	Plasticizers	32
A.11	N-Nitrosamines and N-Nitrosatable substances.....	32
A.12	Polycyclic Aromatic Hydrocarbons (PAHs).....	32
A.13	Alkylphenolethoxylates (APEOs).....	33
A.14	Perfluorinated Compounds.....	33
A.15	Persistent Organic Pollutants (POPs)	33
A.16	Food contact materials	34
A.17	Packaging.....	34
B.1	Introduction.....	35
B.2	General chemical requirements.....	35
B.3	Substances of Very High Concern (SVHC)	35
B.4	CMR substances.....	35
B.5	Certain elements.....	35
B.6	Flame retardants	36

B.7	Colorants	37
B.8	Aniline	38
B.9	Monomers	38
B.10	Solvents (migration)	38
B.11	Solvents (inhalation)	39
B.12	Plasticizers	40
B.13	Sensitizers – Fragrances	40
B.14	N-Nitrosamines and N-Nitrosatable substances	43
B.15	Formaldehyde (other than monomer or preservative)	43
	Bibliography	44

European foreword

This document (CEN/TR 13387-2:2018) has been prepared by Technical Committee CEN/TC 252 “Child care articles”, the secretariat of which is held by AFNOR.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes CEN/TR 13387-2:2015.

The chemical part has been updated compared to the previous edition. Apart from some adaptations necessary as a result of relevant reference documents which have been adopted or changed after the publication of the previous edition of the present guidelines some corrections were made. In addition, the recommendations relating to formaldehyde and preliminary aromatic amines were changed.

The CEN/TR 13387 series comprises the following five parts:

- Safety philosophy and safety assessment (CEN/TR 13387-1);
- Chemical hazards (CEN/TR 13387-2);
- Mechanical hazards (CEN/TR 13387-3);
- Thermal hazards (CEN/TR 13387-4);
- Product information (CEN/TR 13387-5).

CEN/TR 13387-2 is intended to be used in conjunction with CEN/TR 13387-1.

1 Scope

This document provides guidance information on chemical hazards that should be taken into consideration when developing safety standards for child care articles. In addition, these guidelines can assist those with a general professional interest in child safety.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

No terms and definitions are listed in this document.

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

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

4 Regulatory, normative and policy background

4.1 General

In Europe child care articles are covered by the Directive on general product safety (GPSD, Directive 2001/95/EC). This directive contains a general safety requirement and does not address chemical substances in particular. However, Article 13 of the GPSD provides for the opportunity to adopt temporary “emergency” measures which may include limit values for chemical substances in consumer products. Such measures had been adopted for phthalates in toys and child care articles and for dimethylfumarate (DMF) and both have been later incorporated into REACH. In addition, Member States can impose actions on products found unsafe.

Restrictions for several specific chemical substances can be found in Annex XVII of the Regulation concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH, Regulation (EC) No 1907/2006) “relating to restrictions on the marketing and use of certain dangerous substances and preparations” as amended. If applicable to their type of product or material used, these provisions shall be followed by manufacturers of child care articles.

The Regulation on persistent organic pollutants (POP, Regulation (EC) No 850/2004) restricts production, placing on the market and use of chemical substances listed in Annex I of the regulation including constituents of articles. The provisions apply also to child care articles.

Other regulatory provisions relating to chemicals may apply to certain products. For instance, drinking equipment is subject to the Regulation on materials and articles intended to come into contact with food (Regulation (EC) No 1935/2004) and plastics components of drinking equipment are regulated by the Regulation relating to materials and articles intended to come into contact with foodstuffs. A Directive covers the release of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers (Directive 93/11/EEC). Applicable regulation will have to be identified where relevant.

Another example of chemical provisions applicable to child care articles is the Directive on packaging and packaging waste (94/62/EC) which establishes among others limits for lead, cadmium, mercury and hexavalent chromium in packaging.

While not directly applicable to child care articles the Directive on the safety of toys (TSD, 2009/48/EC) is an important reference document addressing a product group with similar exposure characteristics