PD CEN/TR 13387-1:2015

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Child use and care articles — General safety guidelines

Part 1: Safety philosophy and safety assessment

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National foreword

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A list of organizations represented on this committee can be obtained on request to its secretary.

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Child use and care articles - General safety guidelines - Part 1: Safety philosophy and safety assessment

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European foreword

This document (CEN/TR 13387-1:2015) has been prepared by Technical Committee CEN/TC 252 “Child use and 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 [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes CEN/TR 13387:2004.

CEN/TR 13387 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).

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Introduction

This is a revision of CR 13387 first published in 1999. It is a non-normative CEN publication which provides guidance information on common hazards that should be taken into consideration when developing safety standards for child use and care articles.

A general safety philosophy and safety assessment methodology is given in Part 1 of these guidelines together with a collection of anthropometric data.

Chemical hazards are addressed in Part 2. The chemical risk associated with the use of materials for the construction, coating and/or packaging of child use and care articles that may affect children's health are considered.

Mechanical hazards are addressed in Part 3. "Mechanical hazard" is a general designation for physical factors which may give rise to injury due to the mechanical properties of products or parts of products.

Thermal hazards are addressed in Part 4. "Thermal hazards" include hazards associated with flammability and the burning characteristics of materials, contact with hot and cold surfaces, liquids and food, contact with flames, contact with products that melt on heating and overheating or exposure of a child to very low and very high temperatures.

Product information which should be supplied with a child use and care article is addressed in Part 5. "Product information" covers all the documentation and information that should be supplied to ensure the safe use of the product and also the safety of the child using the product.

These guidelines deal with hazards that are common to child use and care articles. They have been drawn-up by a working group of experts set up by CEN TC 252 with the prime objective of harmonizing the approach to hazard and risk assessment and injury prevention. The guidelines give recommendations on preventive safety measures to avoid injuries that could be caused by child use and care articles. If the child use and care article has a protective function, this has to be effective; additionally the product itself has to cause no injury to the child.

The standards being drafted by CEN/TC 252 are for child use and care articles intended for children from birth to 48 months of age who form a very vulnerable group in society. Up to 18 months of age the development of knowledge takes place through the combined use of sensory and motor skills, i.e. children learn to see, hear, taste, smell and feel. Their movements are aimed at achieving familiarity with their environment. As children become older they achieve increased muscular control and balance. Even up to 48 months of age children are unpredictable in their behaviour. Special consideration has to be given to the fact that these children cannot understand how to avoid risks and thus are involuntarily exposed to them.

Child use and care articles constitute a group with large variations between the different products. However many safety hazards associated with this diverse group of products are very similar. These guidelines identify many of these safety hazards and give details that enable similar safety principles to be applied to the drafting of standards across the group of products.

The information given in these guidelines reflects the state of the art at publication. Standards and regulations will continuously be developed. Other sources may also provide useful information for the reader.

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How to use these guidelines

The safety requirements and test methods given are intended to give guidance and to lead to consistency when writing safety standards for child use and care articles. It is recommended to use these guidelines when drafting standards.

In addition, these guidelines can assist those with a general professional interest in child safety.

The safety requirements detailed do not constitute an exhaustive set that can be applied to all child use and care articles. The application to particular products should be evaluated by experts.

In these guidelines rationales are given to explain the potential hazard. Wherever possible, requirements, test equipment and test methods are given which can be used when drafting standards. The terminology in these guidelines is not the one required for standards:, the word *'shall'* has to be used in standards, not *'should'* as given in these guidelines.

CEN/TC 252 is, wherever possible when writing new standards or revising existing standards, drafting their standards on a hazard based format (see for example EN 16120:2012+A1:2014 and EN 1930:2011).

The different parts of the CEN/TR 13387 should enable working groups to draft their standards in a hazard based format by proceeding in the following way:

— identification of the hazards and assessment of the risk;

— definition of the requirements to address an identified hazard and risk;

— definition of relevant test methods to check that the requirements are met;

— provision of an Annex which indicates the rationale for the inclusion of the requirements.

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1 Scope

This Technical Report, contains the general safety philosophy and a guideline on safety assessment that experts are recommended to use when drafting standards.

It also contains an Annex A with a collection of available anthropometric data and details of the abilities of children from birth to 48 months of age.

The general safety philosophy given in this part is based on the principle that child use and care articles should be designed to be safe.

Children with special needs have not been taken into account while drafting these guidelines. ISO/IEC Guide 71 should be consulted to ascertain any further requirements to address the hazards and risks associated with children with special needs.

These guidelines do not cover all types of hazards and risks, such as inappropriate use of products, inadequate supervision of children and products used in a non-domestic situation.

Attention is drawn to the importance of ensuring that all other potential hazards relevant to the product are fully addressed e.g. hygiene, the effects of electrical power etc., where other safety standards may apply.

2 General safety

Safety is often a balance between being safe from injury and the other demands of a child use and care article, for example, ensuring that the item is fit for purpose as well as meeting consumers' needs and expectations.

Attention should be paid to:

— the child's stage of development (ability, weight, age, etc.);

— the intended or foreseeable use of the product, bearing in mind a child's unpredictable behaviour. This unpredictable behaviour exposes children to injury in ways that differ from those of adults, making children a particularly vulnerable group in society;

— the hazard presented by the product in the environment where the product is used.

Child use and care articles should be designed to be safe. Hazards should be eliminated wherever possible. For cases where a hazard cannot be eliminated or sufficiently minimized – by design or safeguards – product related information should be given. However product related information should not be used as an alternative to safe design.

Where the function of a product or part of a product changes by virtue of its use and is beyond the scope of child use and care articles, appropriate requirements should be applied. An example may be a high chair that can be converted into a normal chair.

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3 Terms and definitions

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

3.1
harm
injury or damage to the health of people, or damage to property or the environment

3.2
hazard
potential source of harm

3.3
risk
combination of the probability of occurrence of harm and the severity of that harm

Note 1 to entry: The probability of occurrence includes the exposure to a hazardous situation, the occurrence of a hazardous event, and the possibility to avoid or limit the harm.

3.4
hazard characterisation
quantitative evaluation of the nature of the adverse health effects following exposure to a risk source(s)

3.5
hazard identification
identification of a risk source(s) capable of causing adverse effect(s)

3.6
risk analysis
systematic use of available information to identify hazards and to estimate the risk

3.7
risk evaluation
procedure based on the risk analysis to determine whether tolerable risk has been exceeded

3.8
risk assessment
overall process comprising a risk analysis and a risk evaluation

Note 1 to entry: In practical terms this means the evaluation, including the identification of the related uncertainties, of the likelihood and severity of an adverse effect(s) following exposure under defined means to a risk source(s).

3.9
safety
freedom from risk which is not tolerable

3.10
intended use
use in accordance with information provided together with a product or system, or, in the absence of such information, by generally understood patterns of usage

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4 Accident data

Available accident and injury data should be consulted. The absence of an accident history cannot be a good reason for an automatic presumption of a low level of risk. Other factors should be taken into account, particularly when the possible severity of injury is high.

Appropriate data may not be available for many reasons, including the absence or ineffectiveness of a data collection system, the time delay in collating and presenting statistics, changes in product design and use conditions etc. For example, historical information related to a product or material used in a hot climate may not apply to its use in colder countries or vice versa.

5 Hazard and risk assessment

5.1 Introduction

The approach to hazard risk assessment described in this clause should ensure that the major hazards are assessed when considering child safety within standards.

This clause details a process to identify non-chemical hazards and to assess the risks of injury to children associated with child use and care articles. The assessment of chemical hazards and risks is included in CEN/TR 13387-2.

When developing a new child use and care article safety standard or revising an existing one or working with a standard where child safety needs to be addressed, it is necessary to conduct a hazard and risk assessment. This involves gathering together information from a variety of sources such as accident data, RAPEX and recall notifications, expert opinion and other reliable sources of information. Additionally, reference should be made to relevant child safety guidelines, publications and safety standards.

The hazard risk assessment methodology described in this clause is intended to be used during development or revision of standards; it is not designed to be used solely during product development or for assessment of products on the market.

5.2 Methodology

Separate hazard and risk assessment tables are provided for mechanical hazards, thermal hazards and other non-chemical hazards.

All three tables list the known hazards that have been identified through review of available guides and standards. Additional hazards not listed in the tables may be associated with certain product categories and should also be considered.

Before the hazard and risk assessment tables can be completed, all available data, such as accident data, RAPEX and recall notifications, expert opinion and other reliable sources of information require analysis. There is also a need to fully review the products available and to understand how children will interact with the product. It is also necessary to understand the type of injuries that can occur and how they are caused, as well as how accidents themselves occur and the likely outcomes.

Each table contains the same headings which are explained below:

— The hazard list, based on CEN/TR 13387-3, CEN/TR 13387-4, CEN Guide 12 and ISO/IEC Guide 50.

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— The hazard identification column utilizes available accident data, RAPEX and recall notifications, reported incidents, expert opinion and other reliable sources of information to identify the hazards associated with a product.

— The hazard analysis column indicates the worst-case scenario should an accident occur with the indicated hazard.

— The risk level column indicates the level of risk.

— The risk management measures column identifies those hazards addressed in other similar safety standards, as well as providing the following three options for dealing with the hazard:

  — include safety requirements to address the hazard; or

  — include product information to address the hazard; or

  — there is no need to address the hazard.

  The decision on which option should be taken is based on the information entered in the row and whether or not the hazard is considered a high, medium or low risk.

  Hazards resulting in high or medium risk should be addressed within the standard by safety requirements. Hazards resulting in low risk should be addressed in the standard by safety requirements, providing they do not conflict with the requirements for high or medium risk. Product information should be used to address any hazard that cannot be suitably addressed by safety requirements.

— The comments column is used to explain the rationale and considerations for the decisions indicated in the table and should be systematically filled in for each item in the tables.

Once all the relevant data has been analysed it should be easy to complete the relevant hazard risk analysis table by placing an indication in the relevant boxes. With all the relevant boxes completed in each row of each table it should be possible to draw a conclusion on the level of risk involved with the hazard, as well as what action is needed to address the hazard in the safety standard.

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Table 1 — Mechanical hazards

Hazard list	Hazard identification						Hazard analysis				Risk level	Risk management measures				Comments
	Accident data	RAPEX	Recalls	Reported incidents	Product reports	Expert opinion	Minor or reversible injuries	Serious and reversible or minor and irreversible injuries	Serious and irreversible injuries	Death	L (Low) – M (Medium) – H (High)	Hazard addressed by another similar safety standard or a previous version	Hazard to be addressed by safety requirements	Hazard to be addressed by product information	Hazard not to be addressed	
Hazards from gaps and openings:																
- Entrapment of head and neck																
- Entrapment of fingers																
- Entrapment of limbs																
Hazards due to moving parts, i.e. shearing and compression																
Hazards due to crushing																
Hazards due to protrusions																
Entanglement in cords, ribbons and parts used as ties																
Ingestion hazards																

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