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Safety of toys —

Part 1:

Safety aspects related to mechanical and physical properties

AMENDMENT 2: Impaction and impalement hazards

Sécurité des jouets —

Partie 1: Aspects de sécurité relatifs aux propriétés mécaniques et physiques

AMENDEMENT 2: Risques de blocage liés à l'ingestion

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Foreword

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Amendment 2 to ISO 8124-1:2012 was prepared by Technical Committee ISO/TC 181, *Safety of toys*.

PREVIEW
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Safety of toys — — Part 1: Safety aspects related to mechanical and physical properties - Amendment 2: Impaction and impalement hazards

Replace the existing clause 4.5.1 with the text below:

4.5.1 Squeeze toys, rattles, fasteners and certain other toys and components of toys

4.5.1.1 General

Soft-filled (stuffed) toys or soft-filled parts of toys or parts made entirely of fabric are exempted from the requirements of 4.5.1.

4.5.1.2 Squeeze toys, rattles and certain other toys and components of toys

The requirements of 4.5.1.2 apply to the following types of toys:

- squeeze toys intended for children under 18 months;
- rattles;
- teething toys intended for children under 18 months;
- legs of baby gyms intended for children under 18 months;
- the following toys if they have a mass less than 0,5 kg and are intended for children too young to sit up unaided:
 - removable components of toys intended to be strung across a crib, playpen or perambulator;
 - removable components of baby gyms.

The toys and components of toys listed above shall be designed so that no part of the toy protrudes past the base of test template A, when tested in accordance with 5.3 (Test for shape and size of certain toys).

The toys and components of toys listed above shall, if they have nearly spherical, hemispherical, or circular flared ends, be designed so that such ends do not protrude past the base of the supplemental test template B when tested in accordance with 5.3.

4.5.1.3 Other toys or components of toys with nearly spherical, hemispherical, circular flared or dome shaped ends of toys having a mass less than 0,5 kg and intended for children under 18 months

See Clause E.7

The requirements of 4.5.1.3 apply only to toys or components of toys where the nearly spherical, hemispherical, circular flared or dome shaped end adjoins a shaft, handle or support that has a smaller cross section.

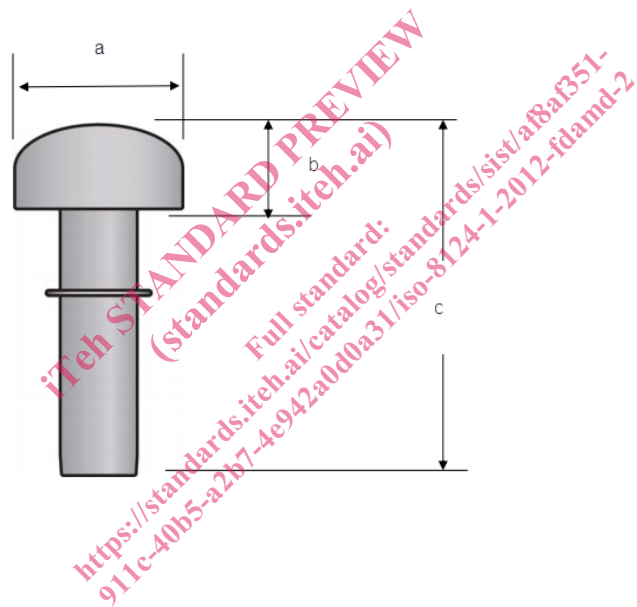
Nearly spherical, hemispherical, circular flared or dome shaped ends of toys or components of toys shall be designed so that such ends do not protrude past the base of the supplemental test template B when tested in accordance with 5.3.

4.5.1.4 Toy fasteners (e.g. nails, bolts, screws and pegs) with nearly spherical, hemispherical or dome shaped ends intended for children 18 months and over but under 48 months

See Clause E.7

The requirements of 4.5.1.4 apply only to toy fasteners that meet all of the following criteria (see figures X and Y):

- The nearly spherical, hemispherical or dome shaped end has a diameter of 15 mm or more
- The distance from the apex of the toy fastener to the undercut is 44,4 mm or less
- The overall length is 57,1 mm or more



Key

- a) Diameter of nearly spherical, hemispherical or dome shaped end ≥ 15 mm
- b) Distance from the apex of the toy fastener to the undercut $\leq 44,4$ mm
- c) Overall length $\geq 57,1$ mm

Figure X – Dimensions of toy fasteners

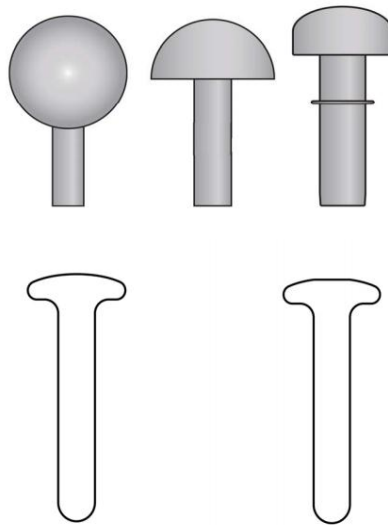


Figure Y – Examples of toy fasteners

The requirements of 4.5.1.4 do not apply to toy fasteners:

- with non-rigid ends, or
- that are tethered to a toy where the weight of the combined toy/fastener is more than 0,5 kg and the length of the tether is less than 300 mm.

Nearly spherical, hemispherical or domed shaped ends of toy fasteners (e.g. nails, bolts, screws and pegs) shall be designed so that such ends do not protrude past the base of the supplemental test template B when tested in accordance with 5.3.

Replace the existing clause 4.8 with the following

4.8 Projections

4.8.1 Projections other than bath toy projections

See Clause E.13.

These requirements are intended to address the hazards associated with the users of toys falling on projections or on rigid components possibly causing skin puncture or internal injury.

If a projection presents a skin puncture hazard, the projection shall be protected by suitable means, such as turning back the end of a wire, or by affixing a smoothly finished protective cap or cover, which effectively increases the surface area for potential contact with the skin. The protective cap or cover shall not become detached when tested in accordance with 5.24 (Reasonably foreseeable abuse tests).

Toys intended to be repeatedly assembled and taken apart shall have the individual pieces and fully assembled articles, as shown on packaging graphics, instructions or other advertising, evaluated separately.

If a rigid handlebar presents a potential internal injury hazard or a skin puncture hazard, it shall be equipped with handle-grips with enlarged ends. Ends of tubes that present a potential internal injury hazard or a skin puncture hazard, shall be equipped with end-plugs or other means of protection at the end of the tube.

Handle-grips, end-plugs and other protective devices shall not become detached when subjected to a removal force of 70 N.

The requirements for the assembled toy do not apply to toys for which the assembling makes up a significant part of the play value of the toy.

Since this requirement relates to hazards arising from a child falling on a toy, only vertical or nearly vertical projections shall be evaluated. However, the toy and its projection shall be tested in the most onerous position.

4.8.2 Bath toy projections

Rigid projections on toys designed primarily for use in the bath tub pose a specific hazard that can result in serious penetration and impalement injuries. Design guidelines are presented in Annex F that intend to minimize penetration and impalement hazards.

As there are no objective means for determining conformance with these guidelines, they are not to be used to judge compliance with this standard.

Replace the existing clause E.7 with the text below.

E.7 Shape, size and strength of certain toys

See 4.5, 4.5.1.3 and 4.5.1.4.

The purpose of the requirements in 4.5 is to identify certain toys which may present impaction, choking and/or suffocation hazards because their design or construction permits them to enter an infant's mouth and potentially become lodged in the throat.

In determining which toys are intended for children who are unable to sit up unaided, or intended for children up to and including 18 months, the following factors are relevant: the manufacturer's stated intent (such as on a label) if it is reasonable, the advertising, the promotion, the marketing and whether the toys are generally considered as suitable for the age group in question.

It is recognised that children start to sit up unaided between 5 months and 10 months of age.

The requirements in 4.5.1.2 are intended to address choking, suffocation and impaction hazards associated with e.g. rattles, teethers, teething toys and squeeze toys intended for children under 18 months.

NOTE The term "nearly" is used below, consistent with the long standing and successful squeeze toy requirement.

The requirements in section 4.5.1.3 (Nearly spherical, hemispherical, circular flared or dome shaped ends of toys or components of toys) are intended to address several deaths and incidents reported through the U.S.Consumer Product Safety Commission, involving young children (under 18 months) playing with various toys featuring spherical ends attached to a handle or shaft. The deaths or incidents resulted from the spherical end of a toy becoming lodged in the child's throat causing asphyxiation. The incidents were similar to those previously addressed by use of the supplemental gauge. The European standard EN 71 was also used as reference as it addresses similar situations. The exclusion for toys weighing over 0,5 kg (1,1 lbs) was incorporated to differentiate the subject toys from other toys as also referenced from the European EN 71 standard.

The requirements in section 4.5.1.4 (Toy fasteners (e.g. nails, bolts, screws and pegs) with nearly spherical, hemispherical or dome shaped ends intended for children 18 months and over but under 48 months) are intended to address toys that meet specific dimension criteria and present a fall-on impaction hazard. The requirements are based on incident data provided by the CPSC involving objects that are long enough to be pushed into the mouth, probably past the uvula in a fall-on incident, and large enough to prevent or inhibit removal, even by an adult caregiver. An otolaryngologist was consulted to review the incident data. The requirements address only toy fasteners because the incident data involved these toy components. A broader scope including all components with this shape, would prohibit many existing toy components that have been widely distributed and used for many years with no known impaction incidents.

Products less than 57,1 mm (the length of the small parts cylinder) in length are excluded as are products less than 15 mm in diameter. These exemptions are based on the dimensions of products in the incident data. Flexible items are exempt because the flexible end assures they will not create a fall-on impaction hazard.

According to a 1992 CPSC Briefing Package "Options to Address Choking Hazards from Small Toy Figures" the actual size of objects known to have choked children are often more meaningful than measurements of children's airways. Several factors contribute to the importance of actual choking data. Individual differences in mouth and throat size, combined with the elasticity of tissue in the mouth and throat, increase the variability of anatomical measurements. Also, anatomical reference points are difficult to standardize and the tissues of patients which have been anesthetized or have died respond (stretch) differently, compared to those in non-anesthetized healthy airway passages.

The impaction hazard addressed by 4.5.1.4 is different from the hazard associated with pre-school play figures addressed in 4.5.4. The preschool play figures were associated with seven deaths by choking and one incident resulting in serious injury. The incidents involved children under the age of 2 with one exception which involved a developmentally delayed child. In addition there were other choking incidents with the pre-school play figures that did not result in significant injury.

The distance to the undercut is based on the dimensions of the small ball test fixture (test template C).

There were a total of 9 cases involving a variety of products in the impaction incident data. Four resulted in fatality, and 1 permanent brain damage. The ages of victims: 7 mo., 9 mo., two children 13 months old, 19 mo., 22 mo., two children aged 2 years, and one child aged 4 years with a severe developmental delay. Included in this incident data were 2 fatalities in 2006 involving the same product (plastic nail) that was age graded 3+. The age grade was verified to be appropriate by experts in the field. The victims in these cases were 19 months and 2 years old. To assure that the requirements of section 4.5.1.4 for toy fasteners addressed the toy that resulted in the 2 fatalities mentioned above, the age grade for this requirement extends to 48 months. This requirement would not prevent future production of the same product if it did not apply to products intended for children under 48 months. There is no need to extend the age grade beyond 48 months since all the incidents are addressed with the stated age grade. Aside from the product involved in the 2006 incidents, all other products involved in this incident data were age graded under 3 years.

There is no force associated with the test because it is not intended to simulate an actual impaction incident. Rather, it is designed to identify the size and shape of products associated with these incidents.

The supplemental gauge (test template B) is used to identify the size and shape of objects associated with incident data and is not related to the size of the child for these incidents. Similarly, the 0,5 kg exemption is related to the weight of objects associated with this type of hazard, not the strength capabilities of children.

The requirements of section 4.5.1.4 do not apply to certain tethered components as specified in the exclusions because the weight of the product and the limited length of the tether make it highly unlikely for the fastener to pose an impaction hazard. Further, the absence of injury data associated with tethered fasteners justifies this exclusion.

The requirements of section 4.5.1.4 do not apply to fasteners with flat tops because the incident data addressed involved nearly spherical, hemispherical or domed ends. Also, the task group evaluated fasteners with flat tops, where millions of units are in distribution without incident data. According to a 1992 CPSC Briefing Package Options to Address Choking Hazards from Small Toy Figures "objects that are round, or that have at least one rounded end, were the most likely to be involved in a choking incident. Objects with flat or pointed ends were less likely to be involved in an incident".

When the requirements for toy fasteners were elaborated, information on a fatality in the United Kingdom with a flat-topped play figure was available. This was a concern, but unfortunately the available data was not detailed enough to justify that the requirements for toy fasteners were expanded to cover also flat-topped items which are not fasteners. If in the future more accident data involving flat-topped items becomes available, the requirements should be revisited.