

Child care articles — Soother holder — Safety requirements and test methods

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ICS 97.190

National foreword

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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 21 and a back cover.

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 252, Child use and care articles, the Secretariat of which is held by AFNOR.

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of an identical text or by endorsement, at the latest by March 2000, and conflicting national standards shall be withdrawn at the latest by March 2000.

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

Introduction

Accidents caused by soothers are few and any resulting in the death of a child are almost unknown. However, a small number of children do die as a result of accidents where a soother is involved, but in these cases death almost always results from strangulation by a cord being used to hang the soother around the child's neck. Such cords are usually either homemade or made for some other purpose, e.g., a coiled keyring holder. Accordingly, a standard for purpose-made soother holders is highly desirable.

This standard is the first for this type of product and its main aim is to eliminate the risk of strangulation. This has only been made possible by severely restricting the length of the holder. The length should be sufficient for the purpose whilst not being so long that the strap, cord, ribbon or chain, etc., could encircle the neck and strangle even the smallest of children.

A strictly functional soother holder, i. e. a pair of undecorated clips joined together by a strap, cord, ribbon or plastic chain, is not to be considered a toy. Making either or both of the clips into simple shapes, with or without decorations by painting or printing, is not sufficient to make the product into a toy. If however, the garment fastener is made more attractive, by for example the addition of a small soft toy, then the entire product becomes a toy as well as being a soother holder.

1 Scope

This European Standard specifies safety requirements relating to the materials, construction, performance, packaging and labelling of soother holders.

It includes test methods for the mechanical and chemical requirements specified.

All products which are intended to be used by a child to connect a soother with any other products are included in the scope of this standard.

There are some products designed for more than one role, for example a soother holder might incorporate a rattle device or a soft toy. Alternatively, the connecting cord might carry a string of decorative coloured beads. Any such products should conform to the requirements of this standard. However, as such products are also toys, the entire product should additionally meet the relevant requirements of EN 71.

2 Normative references

This European standard incorporates by dated or undated references, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments, to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revisions. For undated references the latest edition of the publication referred to applies.

EN 71-1, *Safety of toys - Part 1: Mechanical and physical properties.*

EN 71-3, 1994, *Safety of toys - Part 3: Migration of certain elements.*

EN 1811, *Reference test method for release of nickel from products intended to come into direct and prolonged contact with the skin.*

EN 20105-A03, *Textiles - Tests of colour fastness - Part A03: Grey scale for assessing staining (ISO 105-A03:1993).*

EN ISO 105-E01, *Textiles - Test for colour fastness - Part E01: Colour fastness to water (ISO 105-E01:1994).*

EN ISO 105-E04, *Textiles - Test for colour fastness - Part E04: Colour fastness to perspiration (ISO 105-E04:1994).*

EN ISO 291, *Plastics - Standard atmospheres for conditioning and testing (ISO 291:1997).*

3 Definitions

For the purposes of this standard, the following definitions apply:

3.1

soother holder

article which enables a soother to be secured to a child's garment, etc.

3.2

garment fastener

device for securing the soother holder to a child's garment, etc.

3.3

soother fastener

device for securing the soother holder to the soother

3.4

strap

any connecting device between a garment fastener and the soother fastener

3.5

touch-and-close fastener

device having fibre interlocking faces which are secured when pressed together

3.6

clothing fastener device

part of the garment fastener which attaches it to the clothing

3.7

press stud

fastener with two parts that engage when pressed together

3.8

ventilation holes

holes in the fasteners providing an air passage

NOTE Ventilation holes in the fasteners provide an air passage for the infant to breathe should the infant take the fasteners into and become accidentally lodged in the mouth. The holes also reduce the risk of the fasteners being sucked into the pharynx through the generation of negative pressure.

4 Description of a soother holder

A soother holder may consist of:

- garment fastener (1);
- strap (cord, ribbon, chain etc.) (2);
- soother fastener (3).

NOTE See Figures 1, 2 and 3.

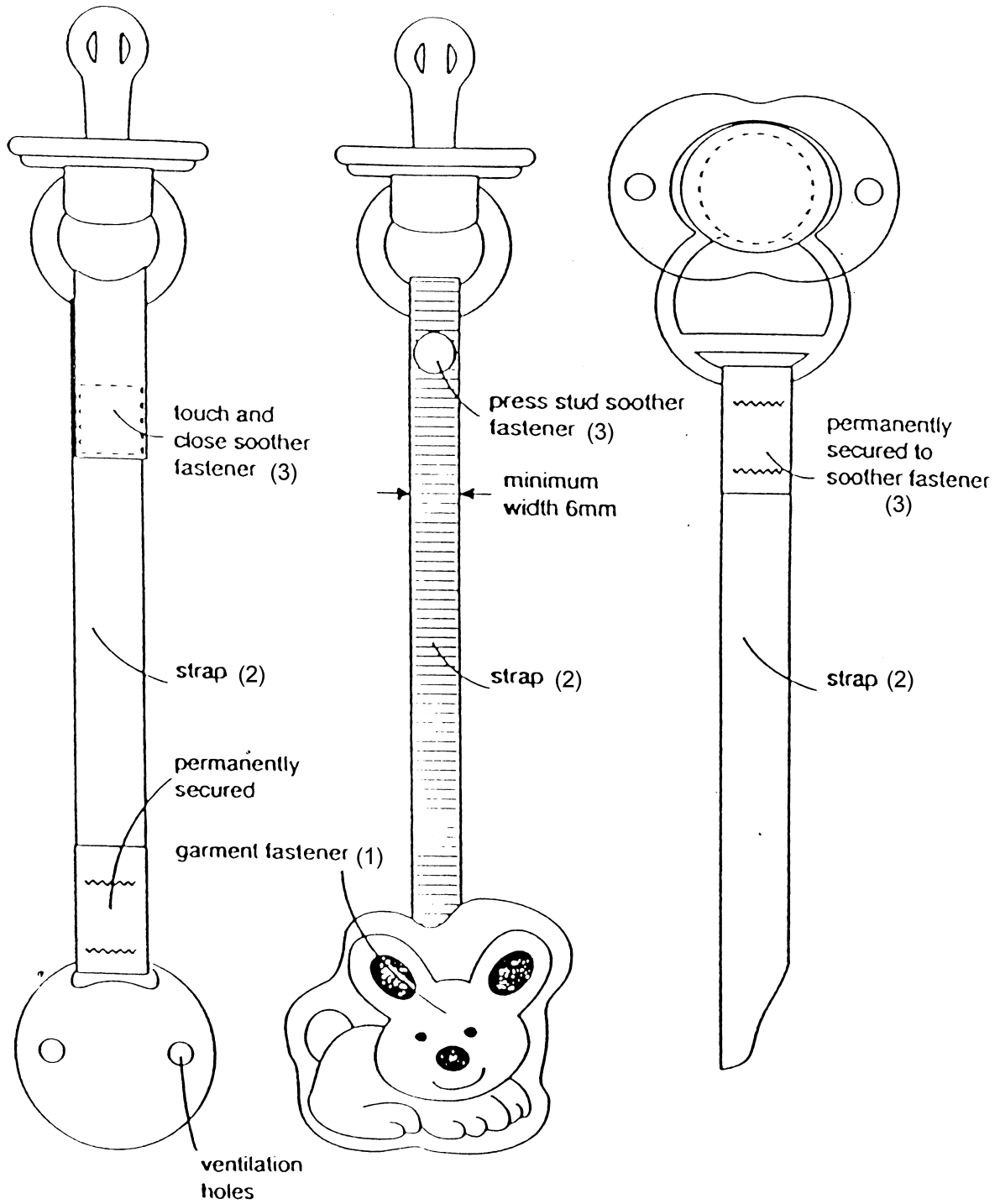


Figure 1 - Examples of soother holders assembled with soothers

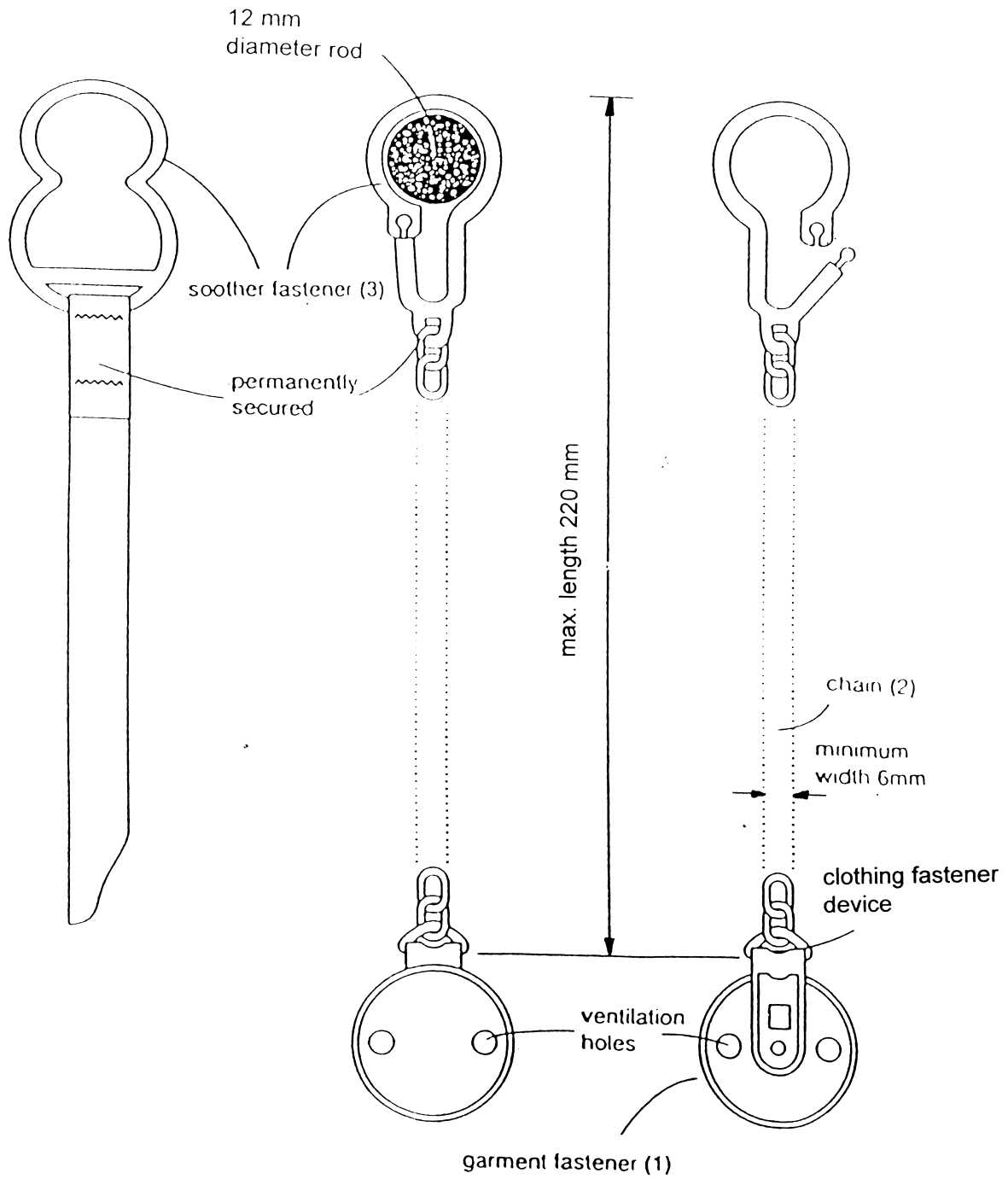


Figure 2 - Examples of soother holders and measurements

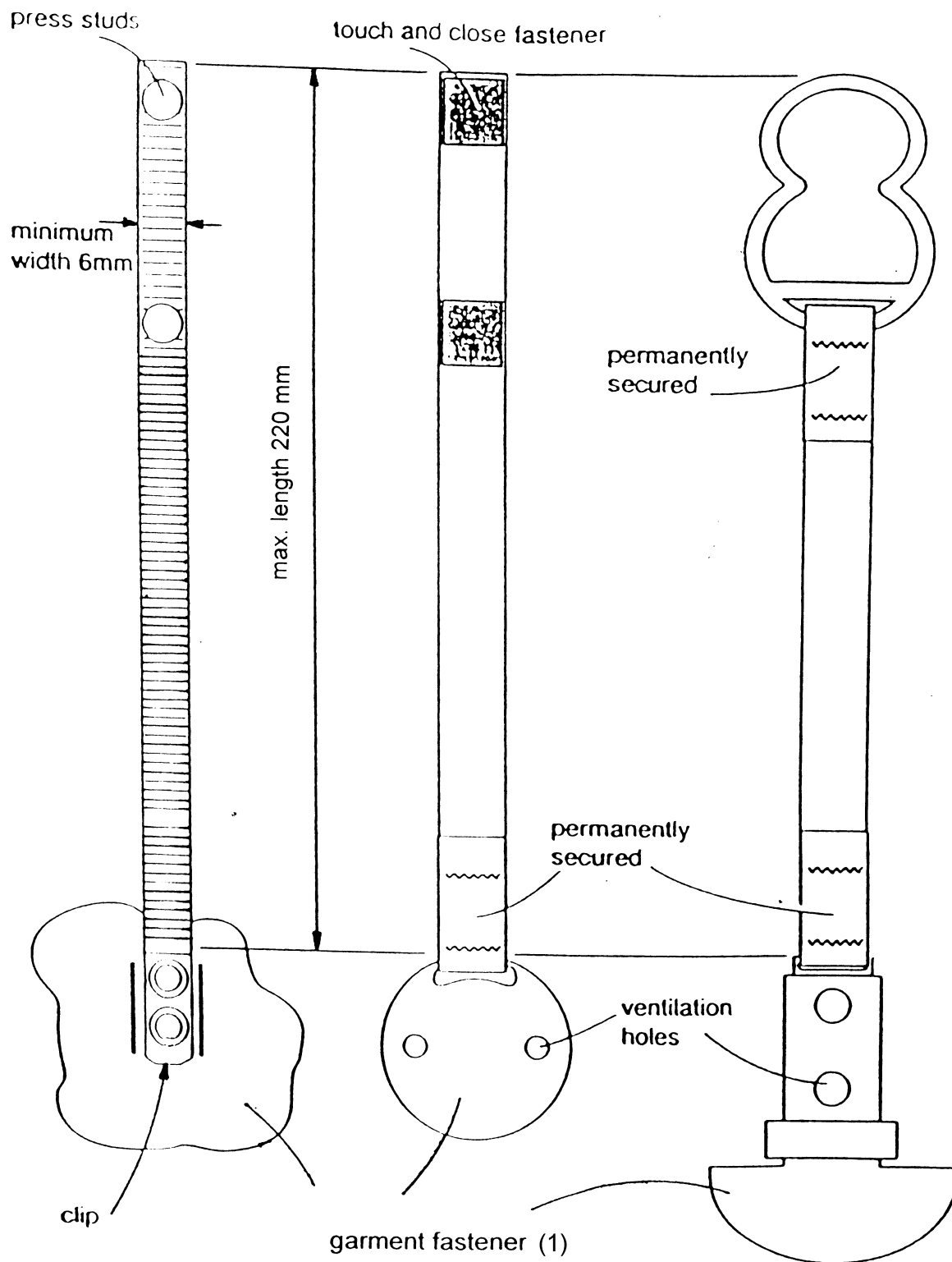


Figure 3 - Examples of soother holders showing their free length

5 Requirements

All materials of construction shall comply with the requirements in this standard.

5.1 General requirements

5.1.1 Small parts

The components of the soother holder shall be so fixed that they cannot become detached when tested in accordance with the test methods given in **6.1.2** to **6.1.6**.

5.1.2 Sharp points and sharp edges

There shall be no accessible non-functional sharp points or sharp edges as defined by the requirements of EN 71-1. The soother holder shall be free from burrs.

5.1.3 Openings (finger traps)

To avoid entrapment of fingers there shall be no accessible openings with a width greater than 5,5 mm and less than 12 mm, unless the depth of penetration is less than 10 mm.

NOTE Circular holes not meeting this requirement present a risk of restricting the circulation. Also, non-circular holes with acute V-shaped angles or inward facing angles that are not well rounded should be avoided.

5.1.4 Decoration

Adhesive decals and labels shall not be attached to any part of the soother holder.

NOTE 1 Adhesive decals and labels will be permitted only when satisfactory test methods have been developed.

NOTE 2 Decorations may be moulded into or imprinted on the soother holder.

5.1.5 Length

A soother holder shall have a maximum length of 220 mm when measured according to **6.1.2**.

5.1.6 Strap

The minimum width of the strap shall be 6 mm when measured according to **6.1.3**.

At least one end shall be permanently attached to one of the fasteners. Permanently attached means:

a) no part shall become detached when tested according to **6.1.6**;

and

b) the strap shall not be capable of being separated from the fastener by undoing a clip, press stud or similar devices, etc., such that the two parts can be reassembled by reversing the procedure.

5.1.7 Maximum size of press stud and touch-and-close fasteners or similar devices

Press stud, touch-and-close fasteners and similar devices shall not be wider than the width of the strap.

Rigid fasteners (press studs and similar devices) shall not have any measurement greater than 9 mm.

NOTE The main types of press studs currently used for soother holders have a maximum measurement of 9 mm.

5.1.8 Size of garment and soother fasteners

Unless a fastener is in the form of press studs or touch-and-close materials, or similar devices (see 5.1.7) it shall pass the “small parts cylinder” test of EN 71-1, any protruding strap being ignored. This requirement shall also apply to the part of a fastener remaining when a detachable fastener has been removed from the strap.

5.1.9 Permanent attachment of fasteners

All fasteners failing the “shape and size of certain toys” test in EN 71-1 (test template A and B) shall be permanently attached to the strap.

If any one fastener passes the “shape and size of certain toys” test in EN 71-1 (test template A and B) it may be detachable.

Even if both fasteners pass the “shape and size of certain toys” test in EN 71-1 (test template A and B) at least one of these fasteners shall be permanently attached to the strap.

Permanently attached means:

- no part shall become detached when tested according to 6.1.6;

and

- the fastener shall not be capable of being separated from the strap by undoing a clip, press stud, touch-and-close fasteners or similar device such that the parts can be reassembled by reversing the procedure.

5.1.10 Ventilation holes in fasteners

If a fastener passes the “shape and size of certain toys” test in EN 71-1 (test template A and B) there shall be no requirement for ventilation holes to be provided.

All other fasteners, except those based on press studs or touch-and-close fasteners or similar devices (see 5.1.7) shall be provided with a ventilation hole or holes.

All ventilation holes shall allow the unhindered passage of a 4 mm diameter rod.

At least 2 ventilation holes, having a total area of at least 40 mm², shall be provided, or 1 ventilation hole allowing the unhindered passage of a 12 mm diameter rod or an area of at least 115 mm² shall be provided.

In all cases, any unventilated surface area encompassing a 25 mm diameter circle shall include at least one ventilation hole.

If the ventilation holes are less than 12 mm diameter the centres of a minimum of 2 of these holes shall be at least 15 mm apart and their edges shall be at least 5 mm from the edge of the fastener.

Ventilation holes not allowing the unhindered passage of a 12 mm diameter rod shall comply with the requirements of 5.1.3.

5.2 Mechanical requirements

5.2.1 Impact resistance

The holder shall be tested as described in 6.1.4 and no part shall break, tear or separate during this test. The tested soother holder shall be used in test 6.1.5.

5.2.2 Durability of the garment fastener

The device used to attach the garment fastener to the clothing shall be tested as described in 6.1.5 and no part shall break or separate during this test or the consecutive tensile strength test.

5.2.3 Tensile strength

After the impact resistance test and the garment fastener durability test, the integrity of the soother holder shall be tested as described in 6.1.6. No part shall break, tear or separate.

5.3 Chemical requirements

5.3.1 Requirements guide by material and other categories

NOTE All plastic parts should be manufactured from materials which comply with Directive 90/128/EEC as amended.

Table 1 - Requirements guide by material and other categories

	Migration of certain elements (5.3.2 and 6.4.1)	Nickel (5.3.3 and 6.4.2)	Colour fastness (5.3.4 and 6.2.3)
Plastic parts	x	-	-
Fabrics, strings, ribbons etc.	x	-	x
Decorations	x	-	x
Metal parts	x	x	-

5.3.2 Migration of certain elements

The migration of certain elements from all materials used in the manufacturing of soother holders shall not exceed the limits given in Table 2 when tested in accordance with 6.2.1.

When soother holders contain parts manufactured from different materials or in different colours, all parts shall be tested individually.

Table 2 - Limits of element migration from soother holder materials

Element	Limit (mg/kg)
Antimony (Sb)	60
Arsenic (As)	25
Barium (Ba)	250
Cadmium (Cd)	50
Lead (Pb)	90
Chromium (Cr)	25
Mercury (Hg)	25
Selenium (Se)	500

5.3.3 Nickel

Nickel shall not be used in products which may come into direct prolonged contact with the skin if the rate of nickel release from the part of the product in direct contact with the skin is greater than $0,5 \mu\text{g}/\text{cm}^2/\text{week}$, when tested according to 6.2.2 (see Directive 94/27/EEC).

NOTE Soother holders may include nickel containing or nickel coated parts, usually the garment fastener and/or connecting rivets. Nickel is a sensitizer which may give rise to allergic reaction.

5.3.4 Colour fastness

The product shall be tested according to 6.2.3. Both colour fastness to water and to perspiration shall have as a requirement a minimum of 4 on the grey scale.

NOTE Textile dyestuffs used in fabrics, strings and ribbons, and also printing inks may contain chemicals which are considered a potential toxicological risk for small children. This risk will be reduced if the dyes are as colour fast as possible.

6 Test methods

6.1 Mechanical tests

6.1.1 Preparation of samples and general testing conditions

All samples shall be conditioned before the tests. The conditioning of the samples shall be performed for at least 40 h in a standard atmosphere in accordance with EN ISO 291, temperature (23 ± 2) °C, and relative humidity (50 ± 5) %. Samples shall remain in the conditioning atmosphere until the test is carried out. The tests can be carried out in a non-conditioned room.

6.1.2 Measurement of length

If the soother is attached to the strap by press studs, touch-and-close fasteners or similar devices, these shall be undone and the measurement shall be made from the end of the free strap to the last piece of strap or flexible attachment device at the garment fastener (see Figure 3).

If the soother is attached to the strap by some type of clip which is permanently attached to the strap, the measurement shall be made from the extreme end of the clip, furthest from the strap, to the last piece of strap or flexible attachment device at the garment fastener (see Figure 2).

In all cases, measurements shall be made under a tensile force of (25 ± 2) N.

6.1.3 Measurement of width

The measurement shall be made with a force of (25 ± 2) N applied along the length of the strap. For a chain, the measurement shall apply to the overall width of a link.

6.1.4 Impact resistance test

Each part of the soother holder shall be tested as follows:

Place the part of the soother holder to be tested unsupported on a flat, horizontal steel surface. Drop a metallic weight with a mass of $(1^{+0,01}_0)$ kg, distributed over an area of diameter (80 ± 2) mm, from a height of (100^{+2}_0) mm above the highest point of the part to be tested so that the centre of the weight is the first point to contact on to each tested part of the holder. The test shall be carried out 5 times on each part of the same sample. The holder shall be placed in different stable orientations before each impact. If either fastener has both stable opened and closed positions, as far as practicable both positions shall be used.

The clothing fastener device on the garment fastener of the product shall then be tested according to 6.1.5.

6.1.5 Garment fastener durability test

The garment fastener is tested using a suitable fixture which opens and closes the device repeatedly. The cycle of the complete movement, i.e. opening and closing, shall be 2 s.

6.1.5.1 Test A

The garment fastener shall first be tested by complete opening and closing, for 1000 cycles. Test A shall be repeated for fasteners which do not incorporate a clamping device.

6.1.5.2 Test B

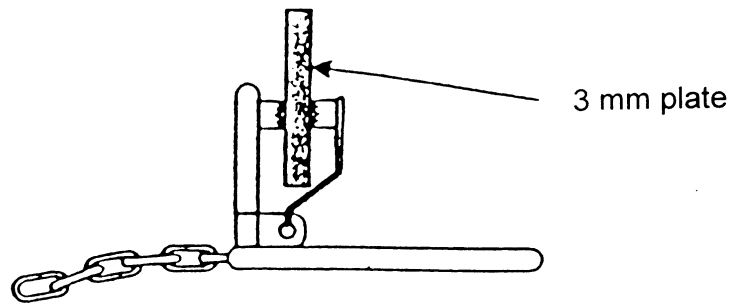
For fasteners with a clamping device, repeat test A but with a 3 mm plate between the jaws, shore hardness SHORE A 40 ± 5 .

The movement shall be as complete as possible. For fasteners which are designed to be completely closed (toggle type, etc.), sufficient force shall be used to fully close the fastener.

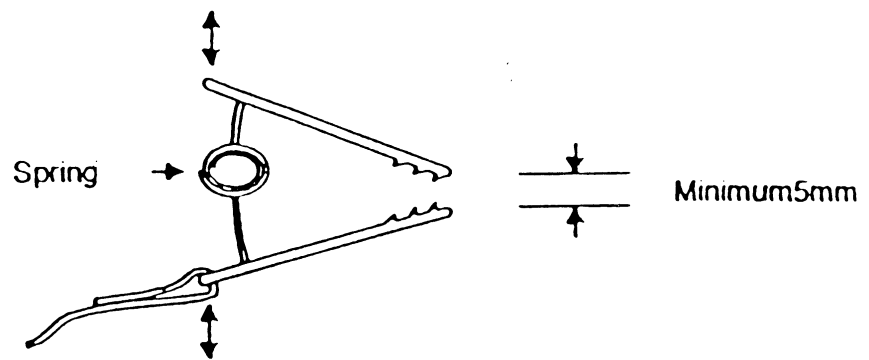
6.1.5.3 Test C

After test A and test B the fastener shall be tested for tensile strength according to **6.1.6**.

a) toggle type



b) closed type



c) open type

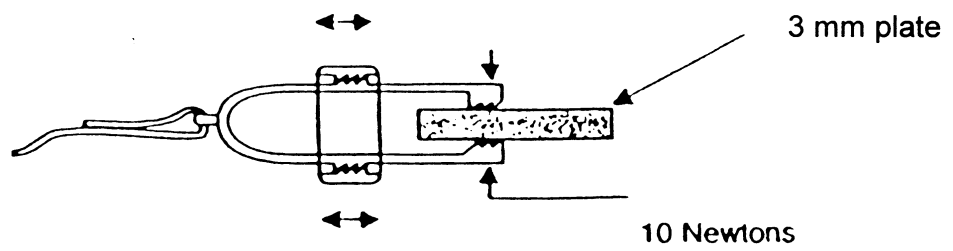


Figure 4 - Examples of garment fastener durability test - Description of measurement

6.1.6 Tensile strength tests

6.1.6.1 General instructions for all tensile strength tests

Parts to be tested shall be held securely by clamps or by such other means as might be required depending on the design of the holder. The tensile force shall be applied to one component of the holder whilst another part is firmly held. A preload of (5 ± 2) N shall be applied to align the specimen and then the force shall be increased to (90 ± 5) N at a crosshead speed of (200 ± 5) mm/min and maintained at that load for $(10 \pm 0,5)$ s. Clamps or other devices shall hold the component securely during the test without giving rise to damage which might affect the test result. Any result where such damage occurs shall be disregarded.

The following pairs of components shall be tested (depending on the design of the soother holder):

- | | | | |
|-----|--------------------------|---|--|
| (1) | garment fastener | - | clothing fastener device |
| (2) | garment fastener | - | far end of strap - strap fully extended (where soother is attached by press studs, etc., or touch-and-close fastener) |
| (3) | soother fastener | - | garment fastener end of strap - strap fully extended (where soother fastener is a separate item permanently attached to the strap) |
| (4) | press studs, etc. | - | strap - adjacent to the stud |
| (5) | touch-and-close fastener | - | strap - adjacent to the fastener |

Additional tests shall be carried out to ensure the integrity of all components.

All single components shall be tested and also every possible combination of pairs of components, if this has not been carried out in other tests.

As the purpose of these series of tests is to reduce the risk of the soother holder coming apart, the force shall be applied in the most onerous position.

6.1.6.2 Test along the length of the holder

Tensile tests shall be carried out on all the above pairs of components (if fitted) by exerting the force along the length of the soother holder. Where the soother fastener is manufactured as a separate item but is permanently fixed to the strap/chain it is permissible for the fastener to open below (90 ± 5) N and this shall not be counted as a failure.

6.1.6.3 Test at right angles to the main axis of the holder

Tensile tests shall be carried out as described in 6.1.6.2 but by holding the garment fastener or soother fastener at right angles to the direction in 6.1.6.2. Depending on the design of the parts of the holder there may be more than one way in which a force can be exerted at right angles to that in 6.1.6.2. Tests shall be carried out in all these directions. Where the soother fastener is manufactured as a separate item but is permanently fixed to the strap/chain it is permissible for the fastener to open below (90 ± 5) N and this shall not be counted as a failure.

If the garment and soother fasteners, which are so large that they pass the "shape and size of certain toys" test in EN 71-1 (test template A and B, see Figure 5), separate during these tests (6.1.6.2 and 6.1.6.3) it shall not count as a failure, unless the separation is a result of a part breaking.

Dimensions in millimetres

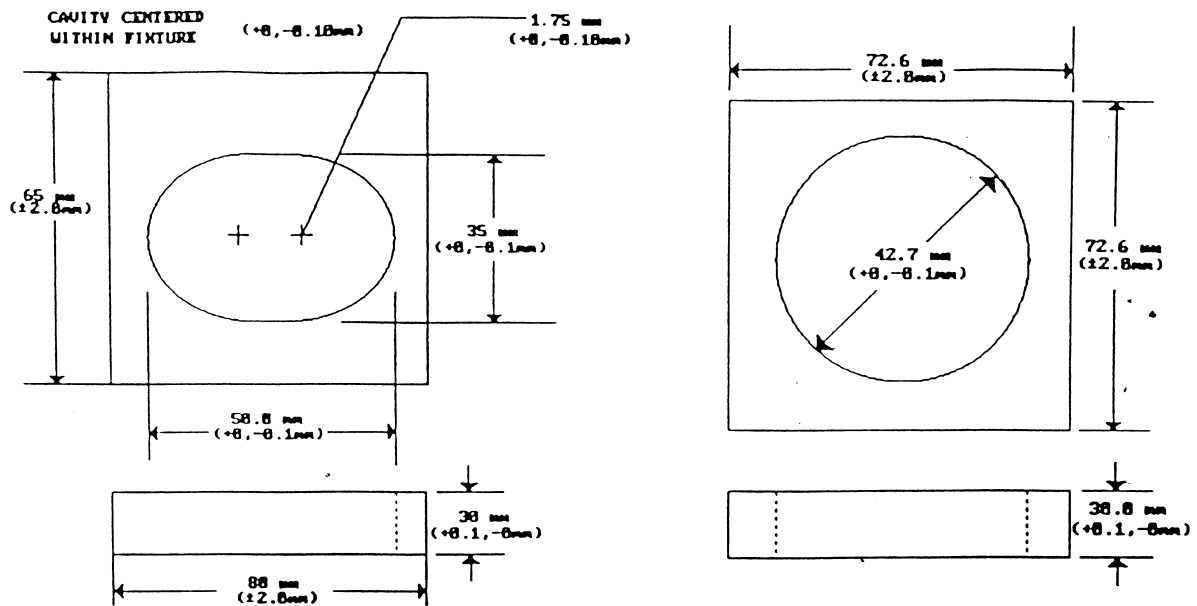


Figure 5 - Test template A and test template B

6.1.7 Test method for openings (finger traps)

Using a 5,5 mm diameter rod measure the penetration of any accessible hole. If the depth of penetration is less than 10 mm then the accessible holes shall not allow the unhindered passage of a 5,5 mm diameter rod, unless the holes allow the unhindered passage of a 12 mm diameter rod.

6.2 Chemical tests

6.2.1 Determination of migration of certain elements

The method stated in EN 71-3:1994 shall be used for the determination of migration of certain elements in soother holders.

NOTE Since EN 71-3:1994 was originally written to cover all possible materials for toys and related products, it is recommended that the following titles and clauses are used when testing soother holders:

Clause	Title
EN 71-3:1994	EN 71-3:1994
5	Principle
6	Reagents and apparatus
6.1	Reagents
6.2	Apparatus
7	Selection of test portions
8	Preparation and analysis of test portions
8.1	Coatings of paints, varnish, lacquer, printing ink, polymer and similar coatings
8.2	Polymeric and similar materials including laminates, whether reinforced textile or not, but excluding other textiles
9	Determination of the quantity of migrated elements
10	Test report

6.2.2 Determination of the release of nickel

Metal parts regardless of coating shall be tested according to EN 1811.

6.2.3 Colour fastness

Colour fastness to water shall be tested according to EN ISO 105-E01 and colour fastness to perspiration shall be tested according to EN ISO 105-E04. The fastness grade determined on the adjacent fabric shall be determined by using the grey scale for assessing staining according to EN 20105-A03.

7 Consumer packaging

The packaging as received by the consumer shall include clear, legible instructions for the use and hygienic care of the soother holder.

These instructions shall be given as described in clause 8 and may be included on a separate leaflet placed inside the packaging or attached to the product.

The consumer packaging shall not include anything which can be used to lengthen the soother holder to more than the stipulated length. This is not intended to preclude the sale of multiple packs of complete soother holders.

8 Product information

8.1 General

The text shall be printed in at least one of the official languages of the country of retail sale. If other languages are included they shall be easy to distinguish.

The print shall be easy to read. Sentences shall be short and of simple construction. The words used shall be uncomplicated and in everyday use.

NOTE It is recommended that products be batch coded.

8.2 Purchase information

The following information shall be visible at the point of retail sale on the outside of the packaging:

- (1) the name, trademark or other means of identification and the address of the manufacturer, distributor or retailer. The particulars may be abbreviated provided that the abbreviation enables the manufacturer, the distributor or the retailer to be identified and easily contacted;
- (2) the number and year of this standard;
- (3) the instructions for use in **8.3**, or if these are included in a leaflet within the packaging, a note indicating that this is the case.

8.3 Instructions for use

The following standard safety sentences shall be provided in the form given:

For your child's safety

WARNING!

Before each use check the whole soother holder. Throw away at the first sign of weariness or damage.

Never lengthen the soother holder!

Never attach it to cords, ribbons, laces or loose parts of clothing. The child may be strangled.

The following instructions shall be provided:

- (1) Information on the safe use of the product;
- (2) A recommendation that the soother holder should only be attached to the garment;
- (3) A recommendation that the soother holder should not be used when the baby is in a cot, bed or crib;
- (4) Method of suitable cleaning;
- (5) Unsuitable methods of cleaning, storage and use.

Annex A

(informative) **Bibliography**

This European Standard incorporates reference to EU Directives. The reference is cited at the appropriate place in the text and the EU Directives are listed hereafter:

Directive 90/128/EEC Commission Directive of 23 February 1990 relating to plastic materials and articles intended to come into contact with foodstuffs.

Directive 94/27/EEC Commission Directive of 30 June 1994 relating to restrictions on the marketing and use of certain dangerous substances and preparations.

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