

Safety of toys —

Part 10: Organic chemical compounds — Sample preparation and extraction

The European Standard EN 71-10:2005 has the status of a
British Standard

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National foreword

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The UK participation in its preparation was entrusted by Technical Committee CW/15, Safety of toys, to Subcommittee CW/15/-/4, Chemical requirements, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep UK interests informed;
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English Version

Safety of toys - Part 10: Organic chemical compounds - Sample preparation and extraction

Sécurité des jouets - Partie 10: Composés chimiques organiques - Procédures de préparation d'échantillon et d'extraction

Sicherheit von Spielzeug - Teil 10: Organisch-chemische Verbindungen - Probenvorbereitung und Extraktion

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Foreword

This European Standard (EN 71-10:2005) has been prepared by Technical Committee CEN/TC 52 "Safety of Toys", the secretariat of which is held by DS.

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of an identical text or by endorsement, at the latest by June 2006, and conflicting national standards shall be withdrawn at the latest by June 2006.

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

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

This European Standard constitutes part 10 of the European Standard on Safety of Toys.

This part should be read in conjunction with parts 9 and 11.

This European Standard defines the sample preparation and extraction procedures used to address potential exposure to organic compounds from ingestion, mouthing, inhalation, skin contact with solids and skin and eye contact with liquids.

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

Introduction

The European Standard EN 71 for safety of toys consists of the following parts:

- Part 1: *Mechanical and physical properties*
- Part 2: *Flammability*
- Part 3: *Migration of certain elements*
- Part 4: *Experimental sets for chemistry and related activities*
- Part 5: *Chemical toys (sets) other than experimental sets*
- Part 6: *Graphical symbols for age warning labelling*
- Part 7: *Finger paints – Requirements and test methods*
- Part 8: *Swings, slides and similar activity toys for indoor and outdoor family domestic use*
- Part 9: *Organic chemical compounds – Requirements*
- Part 10: *Organic chemical compounds – Sample preparation and extraction*
- Part 11: *Organic chemical compounds – Methods of analysis*

The standards EN 71-9, EN 71-10 and EN 71-11 were mandated by the European Commission (M/229) to address the risks presented by organic compounds in toys by taking into account the potential exposure and toxicological effects of those substances considered to present the greatest risk to health.

This European Standard specifies the procedures for preparing and extracting samples of toy materials prior to analysis by the methods described in EN 71-11.

This part should be read in conjunction with EN 71-9, which contains requirements for certain organic compounds in toys, and EN 71-11, which specifies methods of analysis.

This European Standard takes into account the opinion of the Toxicology Section of the Scientific Advisory Committee published in 1992 (EUR 13976), which recommended that certain groups of chemical compounds used in toys and toy materials need to be given special attention. In drafting this European Standard CEN/TC 52 has considered organic chemicals that can be classified within the following groups:

- Solvents
- Preservatives
- Plasticisers (excluding phthalate plasticisers)¹
- Flame retardants
- Monomers
- Biocides (wood preservatives)
- Processing aids
- Colouring agents

During the development of this European Standard, CEN/TC 52 has considered the requirements set out in Council Directive 82/711/EEC as amended and its supporting standards.

¹ Phthalate plasticisers were specifically excluded from the scope of mandate M/229.

1 Scope

This Part 10 of the European Standard EN 71 for safety of toys specifies sample preparation and extraction procedures for establishing the release or content of organic compounds from those toys for which requirements exist in EN 71-9.

2 Normative references

The following referenced documents are indispensable for the application of this European Standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

EN 71-9, *Safety of toys – Part 9: Organic chemical compounds – Requirements*

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

EN 20105-A03, *Textiles – Tests for colour fastness – Part A03: Grey scale for assessing staining*

ISO 105-F10, *Textiles – Tests for colour fastness – Part F10: Specification for adjacent fabric: Multifibre*

3 Terms and definitions

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

3.1 (see B.2)

accessible

contact with the articulated probe when tested in accordance with the 'accessibility-of-a-part-or-component' test in EN 71-1

3.2

accessible liquid

liquid in or on a toy or accompanying a toy to which the child is likely to become exposed during normal or foreseeable use of the toy

NOTE Liquid paints, bubble liquids, ink in pens, liquids provided with toys for squirting are examples of accessible liquids

3.3 (see B.3)

first-action method

method of analysis designed to show the compliance of a toy or toy material with the requirements of EN 71-9 for a particular compound or group of compounds

3.4

final-action method

method of analysis for use when compliance cannot be demonstrated by a *first-action method*

3.5 (see B.4)

laboratory sample

single toy in the form in which it is marketed or intended to be marketed

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3.6

mouth-actuated toy

toy which relies on an action of the mouth to operate and which therefore is designed to come into contact with the mouth during play. Inflatable toys are not considered mouth-actuated toys unless they rely on an action of the mouth after inflation

NOTE Toy whistles, toy imitation novelty teeth are examples of mouth-actuated toys

3.7 (see B.5)

mouthed

licked, sucked and chewed

3.8

paper

material, marketed as either paper or card, with a maximum mass per unit area of 400 g/m²

3.9

polymeric

consisting of plastic, synthetic rubber, natural rubber, silicone polymer but not other natural polymers

3.10

resin-bonded wood

wood-based material

NOTE Plywood, particle board, chipboard and medium-density fibreboard (MDF) are examples of resin-bonded wood

3.11

test portion

portion of the *laboratory sample* prepared for analysis

3.12

textile

woven or knitted fabrics, non-woven fibrous material

NOTE Felt is an example of non-woven fibrous material

3.13

toy material

material from which toys and toy components are made

4 Requirements (see B.6)

Toys, toy components and *toy materials* specified in columns 1 and 2 of Table 1 shall be sampled and analysed in accordance with Clause 5 and the clauses of this European Standard specified in columns 3 to 12 of Table 1.

If a clause number relating to a *first-action method* is given in Table 1 for a particular toy / toy component and *toy material*, compliance with EN 71-9 may be shown by the analysis of the *toy material* by that method alone for the relevant group of organic compounds. A *first-action method* shall not be used to show non-compliance with the requirements of EN 71-9.

Table 1 – Applicable sampling and preparation clauses

| | SPECIFIC TOY/TOY COMPONENT | Toy material | Requirements | | | | | | | | | |
|----|------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|------------------|----------------------------------------|---------------|----------------------|----------------------|-----------------------|--------------|--------------------|---------------|--------------|
| | | | Flame retardants | Colourants and Primary aromatic amines | | Monomers - migration | Solvents - migration | Solvents - inhalation | | Wood preservatives | Preservatives | Plasticisers |
| | | | Procedure | First action | Final action | Procedure | Procedure | First action | Final action | Procedure | Procedure | Procedure |
| 1 | Toys intended to be <i>mouthed</i> by children under 3 years of age | POLYMERIC^a | | | | 6 | 6 | | | | | 6 |
| 2 | Toys, or <i>accessible</i> components of toys, with a mass of 150 g or less intended to be played with in the hands by children under 3 years of age | POLYMERIC^a | | | | 6 | 6 | | | | | 6 |
| 3 | | WOOD | | | 8.3.1 & 8.3.2 | | | | | 8.3.3 | | |
| 4 | | PAPER | | | 8.4.1 & 8.4.2 | | | | | | | |
| 5 | Toys and <i>accessible</i> components of toys intended for children under 3 years of age | TEXTILE | 8.1.1 | 8.1.2 | 8.1.3 & 8.1.4 | | | | | | | |
| 6 | | LEATHER | | | 8.2.1 & 8.2.2 | | | | | | 8.2.3 | |
| 7 | Mouthpiece components of <i>mouth-actuated</i> toys | POLYMERIC^a | | | | 6 | 6 | | | | | 6 |
| 8 | | WOOD | | | 8.3.1 & 8.3.2 | | | | | 8.3.3 | | |
| 9 | | PAPER | | | 8.4.1 & 8.4.2 | | | | | | | |
| 10 | Inflatable toys with a surface greater than 0,5 m ² when fully inflated | POLYMERIC^a | | | | | | 7.1 | 7.2 | | | |
| 11 | Toys worn over the mouth or nose | POLYMERIC^a | | | | 6 | | 7.1 | 7.2 | | | |
| 12 | | TEXTILE | | 8.1.2 | 8.1.3 & 8.1.4 | | | 7.1 | 7.2 | | | |
| 13 | | PAPER | | | 8.4.1 & 8.4.2 | | | | | | | |

Table 1 (continued)

| SPECIFIC TOY/TOY COMPONENT | | Toy material | Requirements | | | | | | | | | |
|----------------------------|----------------------------------------------------------------------------------------|------------------------------|------------------|----------------------------------------|---------------|----------------------|----------------------|-----------------------|--------------|--------------------|---------------|--------------|
| | | | Flame retardants | Colourants and Primary aromatic amines | | Monomers - migration | Solvents - migration | Solvents - inhalation | | Wood preservatives | Preservatives | Plasticisers |
| | | | Procedure | First action | Final action | Procedure | Procedure | First action | Final action | Procedure | Procedure | Procedure |
| 14 | Toys which the child can enter | POLYMERIC^a | | | | | | 7.1 | 7.2 | | | |
| 15 | | TEXTILE | | | | | | 7.1 | 7.2 | | | |
| 16 | Components of graphic instruments sold as toys or used in toys | POLYMERIC^a | | | | 6 | 6 | | | | | 6 |
| 17 | Toys and accessible components of toys for indoor use | WOOD | | | | | | | | 8.3.3 | | |
| 18 | Toys and accessible components of toys for outdoor use | WOOD | | | | | | | | 8.3.3 | | |
| 19 | Toys and components of toys which mimic food | POLYMERIC^a | | | | 6 | 6 | | | | | 6 |
| 20 | Solid toy materials intended to leave a trace | ALL | | | 8.6 | | | | | | | |
| 21 | Coloured <i>accessible liquids</i> in toys | LIQUID | | | 8.5.1 & 8.5.2 | | | | | | | 8.5.3 |
| 22 | Non-coloured <i>accessible liquids</i> in toys | LIQUID | | | | | | | | | | 8.5.3 |
| 23 | Modelling clay, play clay and similar, except those chemical toys addressed by EN 71-5 | ALL | | | 8.7.1 & 8.7.2 | | | | | | | 8.7.3 |
| 24 | Balloon-making compounds | ALL | | | 8.8.1 & 8.8.2 | | | 7.1 | 7.2 | | | |
| 25 | Imitation tattoos with adhesive | ALL | | | 8.9.1 & 8.9.2 | | 6 | | | | | 8.9.3 |
| 26 | Imitation jewellery | POLYMERIC^a | | | | 6 | 6 | | | | | 6 |

^a Excluding polymeric coatings with a thickness of less than 500 µm.

5 Sample preparation

Test portions shall be representative of the toy material in the *laboratory sample*. *Test portions* shall only be taken from *accessible* parts of the toy.

6 Migration – Sampling and extraction

6.1 Simulant (see B.7)

Water, deionized, demonstrably free of appropriate analytes.

6.2 Apparatus

6.2.1 Stainless steel tweezers

6.2.2 Extraction bottles, approximate volume 250 ml with flat base, a screw neck and provided with a PTFE-lined rubber septum.

NOTE Bottles with the following dimensions have been found to be satisfactory²

Outside diameter: 70 mm
 Total height of bottle: 138 mm
 Height from bottom to start of neck: 75 mm
 Inside neck opening: 30 mm

The laboratory shall demonstrate that the containers and closures used do not contribute to or adsorb the substances in question. Glassware and seals on vials and bottles shall be clean, undamaged and free from defects.

6.2.3 Bottle rotator³, capable of holding and rotating the extraction bottles in an end-over-end motion at a constant speed. The distance from the centre of the rotating axis to the centre of the flask shall be approximately 150 mm.

6.3 Sampling

If the approximate surface area of the *laboratory sample* is less than 10 cm², test the sample uncut.

In other cases, select the most appropriate part of the *laboratory sample*, from which to obtain a *test portion* of (10 ± 1) cm², in such a way as to minimize the inaccessible and internal surfaces. Where possible, choose a *test portion* from a thin part of the *laboratory sample*. Remove a disc, or other shaped piece if this reduces the amount of cut edges, with a surface area of (10 ± 1) cm² using a suitable cutting instrument. Measure the approximate surface area of the *test portion* taking into account the thickness when this is greater than 1 mm. The edges of the *test portion* should be smooth in appearance.

In cases where the preparation of the *laboratory sample* leads to unrealistic results because of the cutting process, the whole uncut toy or toy component may be tested using proportionate extraction volumes and apparatus. However, sample sizes of less than 10 cm² shall be extracted using 100 ml of simulant (see B.7).

² Schott Duran is a supplier of a suitable product available commercially. This information is given for the convenience of users of this European Standard and does not constitute an endorsement by CEN.

³ Voor 't Labo, Belgium, is a supplier of a suitable product available commercially. This information is given for the convenience of users of this European Standard and does not constitute an endorsement by CEN.

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Remove any loose particles from the edges of the *test portion*.

If the *test portion* is thin and is likely to stick to the walls of the extraction bottle, pierce a small hole in it and attach a small metallic object through the hole; a paper clip is often appropriate.

6.4 Extraction (see B.8)

Place the *test portion* into the extraction bottle using tweezers. Add 100 ml simulant (6.1) at (20 ± 2) °C. Close the extraction bottle and secure it in the rotator. Rotate the bottle at (60 ± 5) r/min for (60 ± 5) min.

Filter the aqueous migrate in the bottle through a plug of glass wool.

Analyse the aqueous migrate using the appropriate method(s) specified in EN 71-11.

7 Inhalation – Sampling, extraction and analysis

7.1 First-action method for solvents

See A.2 of EN 71-11:2005

7.2 Final-action method for solvents

See A.3 of EN 71-11:2005

8 Specific sampling and extraction procedures

8.1 Textiles – Flame retardants, colourants and primary aromatic amines

8.1.1 Flame retardants

Examine the *laboratory sample* and determine which textile components are present and *accessible*, and have an *accessible* area of 10 cm² or more.

Remove *test portions* from the textile components having an *accessible* area greater than 10 cm² on the toy. The *test portions* may be cut from the *laboratory sample* with a suitable blade. Cut each *test portion* such that no dimension exceeds 3 mm. Store each *test portion* separately in a suitable container.

Weigh, to the nearest 1 mg, approximately 0,5 g of the *test portion* into a 20-ml amber glass vial with a PTFE-liner screw cap. Add 5 ml acetonitrile and place the vial in an ultrasonic bath for 60 min at 40 °C. Filter the extract, transfer to a vial and crimp.

Analyse the extract in accordance with 5.2 of EN 71-11:2005.

8.1.2 First-action method for colourants and primary aromatic amines

This test, specified in Annex A and based on EN ISO 105-E04, is an assessment of whether any colourants can be transferred from textile toy materials to the mouth, mucous membranes or skin. If textiles are found not to be colourfast when tested in accordance with the test procedure described in Annex A, they shall be tested by the *final-action method* for colourants (8.1.3) and the *final-action method* for primary aromatic amines (8.1.4).

8.1.3 Final-action method for colourants

Examine the *laboratory sample* and determine which textile components are present and *accessible*, and have an *accessible* area of 10 cm² or more. Different colours of the same textile material shall be treated separately.

Remove *test portions* from the textile components having an *accessible* area greater than 10 cm² on the toy. Components which have stained the multifibre fabric in the *first-action method* for textiles (8.1.2) shall be tested if their area is greater than 1 cm².

The *test portions* may be cut from the *laboratory sample* with a suitable blade. Cut each *test portion* such that no dimension exceeds 3 mm. Store each *test portion* separately in a suitable container.

Weigh, to the nearest 1 mg, approximately 0,5 g of the *test portion* into a 40-ml amber glass vial with a PTFE-liner screw cap. Add 10 ml ethanol and place the vial in an ultrasonic bath for 15 min. Transfer the extract into a test tube and concentrate to about 1 ml under a stream of air or nitrogen. Filter the extract, transfer to a 2-ml vial and crimp.

Analyse the extract in accordance with 5.3 of EN 71-11:2005.

8.1.4 Final-action method for primary aromatic amines

Obtain *test portions* of the *laboratory sample* in the same way as detailed in 8.1.3.

Weigh, to the nearest 1 mg, approximately 1,0 g of the *test portion* into a 50-ml polypropylene tube. Add 15 ml water (6.1) and agitate on a Vortex[®] mixer for 30 s.

Centrifuge the tube at 2 000 g for 15 min. Pour the supernatant liquid onto a porous kieselguhr column⁴ and allow it to absorb for 20 min.

Extract the kieselguhr with 2 x 40 ml *tert*-butyl methyl ether. Combine the eluates in a 100-ml round-bottomed flask and evaporate at 50 °C to approximately 5 ml using a rotary evaporator.

Transfer the ether extract to a graduated 10-ml test tube and then carefully reduce to 1 ml under a gentle stream of nitrogen at ambient temperature. Transfer the concentrated extract to a 2-ml vial and crimp.

NOTE 1 It should be avoided evaporating the ether extract to dryness as this has been shown to adversely affect amine recovery.

NOTE 2 The recovery of amines can be improved by converting them to their hydrochloride salts.

Analyse the extract in accordance with 5.4 of EN 71-11:2005.

8.2 Leather – Colourants, primary aromatic amines and preservatives

8.2.1 Colourants

Examine the *laboratory sample* and determine which leather components are present and *accessible*, and have an *accessible* area of 10 cm² or more. Different coloured leathers shall be treated separately.

⁴ SPE column Chromabond XTR, 70 ml, 14,5 g, is an example of a suitable product available commercially. This information is given for the convenience of users of this European Standard and does not constitute an endorsement by CEN.

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Remove *test portions* from the leather components having an *accessible* area greater than 10 cm² on the toy. The *test portions* may be cut from the *laboratory sample* with a suitable blade. Cut each *test portion* such that no dimension exceeds 3 mm. Store each *test portion* separately in a suitable container.

Weigh, to the nearest 1 mg, approximately 0,5 g of the *test portion* into a 40-ml amber glass vial with a PTFE-liner screw cap. Add 10 ml ethanol and place the vial in an ultrasonic bath for 15 min. Transfer the extract into a test tube and concentrate to about 1 ml under a stream of air. Filter the extract, transfer to a 2-ml vial and crimp.

Analyse the extract in accordance with 5.3 of EN 71-11:2005.

NOTE Leather samples are assumed not to be colourfast, and are therefore not subjected to a *first-action* method.

8.2.2 Primary aromatic amines

Obtain *test portions* of the *laboratory sample* in the same way as detailed in 8.2.1.

Weigh, to the nearest 1 mg, approximately 1,0 g of the *test portion* into a 50-ml polypropylene tube. Add 15 ml water (6.1) and agitate on a Vortex[®] mixer for 30 s.

Centrifuge the tube at 2 000 g for 15 min. Pour the supernatant liquid onto a porous kieselguhr column⁴ and allow it to absorb for 20 min.

Extract the kieselguhr with 2 x 40 ml *tert*-butyl methyl ether. Combine the eluates in a 100-ml round-bottomed flask and evaporate at 50 °C to approximately 5 ml using a rotary evaporator.

Transfer the ether extract to a 10-ml test tube and then carefully reduce to 1 ml under a gentle stream of nitrogen at ambient temperature. Transfer the concentrated extract to a 2-ml vial and crimp.

NOTE 1 It should be avoided evaporating the ether extract to dryness as this has been shown to adversely affect amine recovery.

NOTE 2 The recovery of amines can be improved by converting them to their hydrochloride salts.

Analyse the extract in accordance with 5.4 of EN 71-11:2005.

8.2.3 Preservatives

Obtain *test portions* of the *laboratory sample* in the same way as detailed in 8.2.1.

Weigh, to the nearest 1 mg, approximately 1,0 g of the *test portion* into a 50-ml polypropylene tube. Add 15 ml water (6.1) and agitate on a Vortex[®] mixer for 30 s. Pour the liquid into a suitable container.

Analyse the extract in accordance with 5.7 of EN 71-11:2005; 5.5.2 of EN 71-11:2005, the method for phenol; and the method in the relevant EU Directive for the identification and determination of free formaldehyde in cosmetic products.

NOTE Commission Directive 90/207/EEC refers.

⁴ SPE column Chromabond XTR, 70 ml, 14,5 g, is an example of a suitable product available commercially. This information is given for the convenience of users of this European Standard and does not constitute an endorsement by CEN.

8.3 Wood – Colourants, primary aromatic amines and wood preservatives

8.3.1 Colourants

If the thickness of the wooden toy or wooden component is less than 1 cm, obtain a *test portion* from the wood representative of the whole *accessible* surface, such that no dimension of the *test portion* shall exceed 3 mm. Obtain at least a 5-g *test portion* and store in a suitable container.

If the thickness of the wooden toy or wooden component is greater than 1 cm, drill into the wood using a suitable drill bit to a depth of approximately 1 cm, ensuring that the drillings are distributed evenly over the *accessible* surface. Collect at least a 5-g *test portion* of the shavings produced by the drillings and store in a suitable container.

Weigh, to the nearest 1 mg, approximately 0,5 g of the *test portion* into a 40-ml amber glass vial with a PTFE-liner screw cap. Add 10 ml ethanol and place the vial in an ultrasonic bath for 15 min. Transfer the extract into a test tube and concentrate to about 1 ml under a stream of air or nitrogen. Filter the extract, transfer to a 2-ml vial and crimp.

Analyse the extract in accordance with 5.3 of EN 71-11:2005.

8.3.2 Primary aromatic amines

Obtain *test portions* of the *laboratory sample* in the same way as detailed in 8.3.1.

Weigh, to the nearest 1 mg, approximately 1,0 g of the *test portion* into a 50-ml polypropylene tube. Add 15 ml water (6.1) and agitate on a Vortex[®] mixer for 30 s.

Centrifuge the tube at 2 000 g for 15 min. Pour the supernatant liquid onto a porous kieselguhr column⁴ and allow it to absorb for 20 min.

Extract the kieselguhr with 2 x 40 ml *tert*-butyl methyl ether. Combine the eluates in a 100-ml round-bottomed flask and evaporate at 50 °C to approximately 5 ml using a rotary evaporator.

Transfer the ether extract to a 10-ml test tube and then carefully reduce to 1 ml under a gentle stream of nitrogen at ambient temperature. Transfer the concentrated extract to a 2-ml vial and crimp.

NOTE 1 It should be avoided evaporating the ether extract to dryness as this has been shown to adversely affect amine recovery.

NOTE 2 The recovery of amines can be improved by converting them to their hydrochloride salts.

Analyse the extract in accordance with 5.4 of EN 71-11:2005.

8.3.3 Wood preservatives

Obtain *test portions* of the *laboratory sample* in the same way as detailed in 8.3.1.

Weigh, to the nearest 1 mg, approximately 2,5 g of the test portion into a 50-ml conical flask with ground glass stopper. Add 25 ml of a carefully mixed (9+1) ethanol / glacial acetic acid solution, stopper and place the flask in an ultrasonic bath for 1 h. Allow the flask to cool to room temperature, filter and store the extract in a suitable container.

⁴ SPE column Chromabond XTR, 70 ml, 14,5 g, is an example of a suitable product available commercially. This information is given for the convenience of users of this European Standard and does not constitute an endorsement by CEN.

Analyse the extract in accordance with 5.6 of EN 71-11:2005.

8.4 Paper – Colourants and primary aromatic amines

8.4.1 Colourants

Examine the *laboratory sample* and determine which paper components are present and *accessible*, and have an *accessible* area of 10 cm² or more. Different coloured papers shall be treated separately.

Remove *test portions* from the paper components having an *accessible* area greater than 10 cm² on the toy. The *test portions* may be cut from the *laboratory sample* with a suitable blade. Cut each *test portion* such that no dimension exceeds 3 mm. Store each *test portion* separately in a suitable container.

Weigh, to the nearest 1 mg, approximately 0,5 g of the *test portion* into a 40-ml amber glass vial with a PTFE-liner screw cap. Add 10 ml ethanol and place the vial in an ultrasonic bath for 15 min. Transfer the extract into a test tube and concentrate to about 1 ml under a stream of air or nitrogen. Filter the extract, transfer to a 2-ml vial and crimp.

Analyse the extract in accordance with 5.3 of EN 71-11:2005.

8.4.2 Primary aromatic amines

Obtain *test portions* of the *laboratory sample* in the same way as detailed in 8.4.1.

Weigh, to the nearest 1 mg, approximately 1,0 g of the *test portion* into a 50-ml polypropylene tube. Add 15 ml water (6.1) and agitate on a Vortex[®] mixer for 30 s.

Centrifuge the tube at 2 000 g for 15 min. Pour the supernatant liquid onto a porous kieselguhr column⁴ and allow it to absorb for 20 min.

Extract the kieselguhr with 2 x 40 ml *tert*-butyl methyl ether. Combine the eluates in a 100-ml round-bottomed flask and evaporate at 50 °C to approximately 5 ml using a rotary evaporator.

Transfer the ether extract to a 10-ml test tube and then carefully reduce to 1 ml under a gentle stream of nitrogen at ambient temperature. Transfer the concentrated extract to a 2-ml vial and crimp.

NOTE 1 It should be avoided evaporating the ether extract to dryness as this has been shown to adversely affect amine recovery.

NOTE 2 The recovery of amines can be improved by converting them to their hydrochloride salts.

Analyse the extract in accordance with 5.4 of EN 71-11:2005.

8.5 Aqueous liquids - Colourants, primary aromatic amines and preservatives

8.5.1 Colourants

Remove the liquid from the *laboratory sample* ensuring that the *test portion* removed represents the whole of the liquid in the *laboratory sample*. Different coloured liquids shall be treated separately.

⁴ SPE column Chromabond XTR, 70 ml, 14,5 g, is an example of a suitable product available commercially. This information is given for the convenience of users of this European Standard and does not constitute an endorsement by CEN.

Depending on the intensity of the colour, weigh, to the nearest 1 mg, 0,1 g to 0,5 g of the *test portion* into a 40-ml amber glass vial with a PTFE-liner screw cap. Add 10 ml ethanol and place the vial in an ultrasonic bath for 15 min. Transfer the extract into a test tube and concentrate to about 1 ml under a stream of air. Filter the extract, transfer to a 2-ml vial and crimp.

NOTE This step can be omitted for non-viscous, faintly coloured liquids, in which case the *test portion* is analysed directly in accordance with 5.3 of EN 71-11:2005.

Analyse the extract in accordance with 5.3 of EN 71-11:2005.

8.5.2 Primary aromatic amines

Remove the liquid from the *laboratory sample* ensuring that the *test portion* removed represents the whole of the liquid in the *laboratory sample*. Different coloured liquids shall be treated separately.

Weigh, to the nearest 1 mg, approximately 1,0 g of the *test portion* into a 50-ml polypropylene tube. Add 15 ml water (6.1) and agitate on a Vortex[®] mixer for 30 s.

Pour the liquid onto a porous kieselguhr column⁴ and allow it to absorb for 20 min.

Extract the kieselguhr with 2 x 40 ml *tert*-butyl methyl ether. Combine the eluates in a 100-ml round-bottomed flask and evaporate at 50 °C to approximately 5 ml using a rotary evaporator.

Transfer the ether extract to a 10-ml test tube and then carefully reduce to 1 ml under a gentle stream of nitrogen at ambient temperature. Transfer the concentrated extract to a 2-ml vial and crimp.

NOTE 1 It should be avoided evaporating the ether extract to dryness as this has been shown to adversely affect amine recovery.

NOTE 2 The recovery of amines can be improved by converting them to their hydrochloride salts.

Analyse the extract in accordance with 5.4 of EN 71-11:2005.

8.5.3 Preservatives

Remove the liquid from the *laboratory sample* ensuring that the *test portion* removed represents the whole of the liquid in the *laboratory sample*. Different coloured liquids shall be treated separately.

Weigh, to the nearest 1 mg, approximately 1,0 g of the *test portion* into a 50-ml polypropylene tube. Add 15 ml water (6.1) and agitate on a Vortex[®] mixer for 30 s.

Pour the supernatant liquid into a suitable container.

Analyse the extract in accordance with 5.7 of EN 71-11:2005; 5.5.2 of EN 71-11:2005, the method for phenol; and the method in the relevant EU Directive for the identification and determination of free formaldehyde in cosmetic products.

NOTE Commission Directive 90/207/EEC refers.

⁴ SPE column Chromabond XTR, 70 ml, 14,5 g, is an example of a suitable product available commercially. This information is given for the convenience of users of this European Standard and does not constitute an endorsement by CEN.

8.6 Solid toy materials intended to leave a trace - Colourants and primary aromatic amines

8.6.1 Colourants

Remove the solid toy material intended to leave a trace from the *laboratory sample*. Finely divide the material and store in a suitable container. Different coloured materials shall be treated separately.

Weigh, to the nearest 1 mg, approximately 0,5 g of the *test portion* in a 40-ml amber glass vial with a PTFE-liner screw cap. Add 10 ml ethanol and place the vial in an ultrasonic bath for 15 min. Transfer the extract into a test tube and concentrate to about 1 ml under a stream of air. Filter the extract, transfer to a 2-ml vial and crimp.

Analyse the extract in accordance with 5.3 of EN 71-11:2005.

8.6.2 Primary aromatic amines

Remove the solid toy material intended to leave a trace from the laboratory sample. Finely divide the material and store in a suitable container. Different coloured materials shall be treated separately.

Weigh, to the nearest 1 mg, approximately 1,0 g of the test portion into a 50-ml polypropylene tube. Add 15 ml water (6.1) and agitate on a Vortex[®] mixer for 30 s.

Centrifuge the tube at 2 000 g for 15 min. Pour the supernatant liquid onto a porous kieselguhr column⁴ and allow it to absorb for 20 min.

Extract the kieselguhr with 2 x 40 ml *tert*-butyl methyl ether. Combine the eluates in a 100-ml round-bottomed flask and evaporate at 50 °C to approximately 5 ml using a rotary evaporator.

Transfer the ether extract to a 10-ml test tube and then carefully reduce to 1 ml under a gentle stream of nitrogen at ambient temperature. Transfer the concentrated extract to a 2-ml vial and crimp.

NOTE 1 It should be avoided evaporating the ether extract to dryness as this has been shown to adversely affect amine recovery.

NOTE 2 The recovery of amines can be improved by converting them to their hydrochloride salts.

Analyse the extract in accordance with 5.4 of EN 71-11:20035

8.7 Modelling clay, play clay and similar - Colourants, primary aromatic amines and preservatives

8.7.1 Colourants

Remove the modelling clay, play clay or similar material from the *laboratory sample*. Homogenize the *test portion* and store in a suitable container. Different coloured materials shall be treated separately.

Weigh, to the nearest 1 mg, approximately 0,5 g of the *test portion* in a 40-ml amber glass vial with a PTFE-liner screw cap. Add 10 ml ethanol and place the vial in an ultrasonic bath for 15 min. Transfer the extract into a test tube and concentrate to about 1 ml under a stream of air. Filter the extract, transfer to a 2-ml vial and crimp.

⁴ SPE column Chromabond XTR, 70 ml, 14,5 g, is an example of a suitable product available commercially. This information is given for the convenience of users of this European Standard and does not constitute an endorsement by CEN.

Analyse the extract in accordance with 5.3 of EN 71-11:2005.

8.7.2 Primary aromatic amines

Remove the modelling clay, play clay or similar material from the *laboratory sample*. Homogenize the *test portion* and store in a suitable container. Different coloured materials shall be treated separately.

Weigh, to the nearest 1 mg, approximately 1,0 g of the *test portion* into a 50-ml polypropylene tube. Add 15 ml water (6.1) and agitate on a Vortex® mixer for 30 s.

Centrifuge the tube at 2 000 g for 15 min. Pour the supernatant liquid onto a porous kieselguhr column⁴ and allow it to absorb for 20 min.

Extract the kieselguhr with 2 x 40 ml *tert*-butyl methyl ether. Combine the eluates in a 100-ml round-bottomed flask and evaporate at 50 °C to approximately 5 ml using a rotary evaporator.

Transfer the ether extract to a 10-ml test tube and then carefully reduce to 1 ml under a gentle stream of nitrogen at ambient temperature. Transfer the concentrated extract to a 2-ml vial and crimp.

NOTE 1 It should be avoided evaporating the ether extract to dryness as this has been shown to adversely affect amine recovery.

NOTE 2 The recovery of amines can be improved by converting them to their hydrochloride salts.

Analyse the extract in accordance with 5.4 of EN 71-11:2005.

8.7.3 Preservatives

Remove the modelling clay, play clay or similar material from the *laboratory sample*. Homogenize the *test portion* and store in a suitable container. Different coloured materials shall be treated separately.

Weigh, to the nearest 1 mg, approximately 5,0 g of the *test portion* into a 50-ml polypropylene tube. Add 15 ml water (6.1) and agitate on a Vortex® mixer for 30 s.

Centrifuge the tube at 2 000 g for 15 min. Pour the supernatant liquid into a suitable container.

Analyse the extract in accordance with 5.7 of EN 71-11:2005; 5.5.2 of EN 71-11:2005, the method for phenol; and the method in the relevant EU Directive for the identification and determination of free formaldehyde in cosmetic products.

NOTE Commission Directive 90/207/EEC refers.

8.8 Balloon-making compounds – Colourants and primary aromatic amines

8.8.1 Colourants

Remove the balloon-making compound from the *laboratory sample*. Homogenize the *test portion* and store in a suitable container. Different coloured compounds shall be treated separately.

Weigh, to the nearest 1 mg, approximately 0,5 g of the *test portion* in a 40-ml amber glass vial with a PTFE-liner screw cap. Add 10 ml ethanol and place the vial in an ultrasonic bath for 15 min. Transfer the extract

⁴ SPE column Chromabond XTR, 70 ml, 14,5 g, is an example of a suitable product available commercially. This information is given for the convenience of users of this European Standard and does not constitute an endorsement by CEN.

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into a test tube and concentrate to about 1 ml under a stream of air. Filter the extract, transfer to a 2-ml vial and crimp.

Analyse the extract in accordance with 5.3 of EN 71-11:2005.

8.8.2 Primary aromatic amines

Remove the balloon-making compound from the *laboratory sample*. Homogenize the *test portion* and store in a suitable container. Different coloured compounds shall be treated separately.

Weigh, to the nearest 1 mg, approximately 1,0 g of the *test portion* into a 50-ml polypropylene tube. Add 15 ml water (6.1) and agitate on a Vortex® mixer for 30 s.

Centrifuge the tube at 2 000 g for 15 min. Pour the supernatant liquid onto a porous kieselguhr column⁴ and allow it to absorb for 20 min.

Extract the kieselguhr with 2 x 40 ml *tert*-butyl methyl ether. Combine the eluates in a 100-ml round-bottomed flask and evaporate at 50 °C to approximately 5 ml using a rotary evaporator.

Transfer the ether extract to a 10-ml test tube and then carefully reduce to 1 ml under a gentle stream of nitrogen at ambient temperature. Transfer the concentrated extract to a 2-ml vial and crimp.

NOTE 1 It should be avoided evaporating the ether extract to dryness as this has been shown to adversely affect amine recovery.

NOTE 2 The recovery of amines can be improved by converting them to their hydrochloride salts.

Analyse the extract in accordance with 5.4 of EN 71-11:2005.

8.9 Imitation tattoos with adhesive - Colourants, primary aromatic amines and preservatives

8.9.1 Colourants

Examine the *laboratory sample* and determine which colours are present on the imitation tattoo(s).

Remove *test portions* from the imitation tattoo(s) so that each colour present is sampled. Cut each *test portion* such that no dimension exceeds 3 mm. Store each *test portion* separately in a suitable container.

Weigh, to the nearest 1 mg, approximately 0,5 g of the *test portion* in a 40-ml amber glass vial with a PTFE-liner screw cap. Add 10 ml ethanol and place the vial in an ultrasonic bath for 15 min. Transfer the extract into a test tube and concentrate to about 1 ml under a stream of air. Filter the extract, transfer to a 2-ml vial and crimp.

Analyse the extract in accordance with 5.3 of EN 71-11:2005.

8.9.2 Primary aromatic amines

Obtain *test portions* of the *laboratory sample* in the same way as detailed in 8.9.1.

Weigh, to the nearest 1 mg, approximately 1,0 g of the *test portion* into a 50-ml polypropylene tube. Add 15 ml water (6.1) and agitate on a Vortex® mixer for 30 s.

⁴ SPE column Chromabond XTR, 70 ml, 14,5 g, is an example of a suitable product available commercially. This information is given for the convenience of users of this European Standard and does not constitute an endorsement by CEN.

Centrifuge the tube at 2 000 g for 15 min. Pour the supernatant liquid onto a porous kieselguhr column⁴ and allow it to absorb for 20 min.

Extract the kieselguhr with 2 x 40 ml *tert*-butyl methyl ether. Combine the eluates in a 100-ml round-bottomed flask and evaporate at 50 °C to approximately 5 ml using a rotary evaporator.

Transfer the ether extract to a 10-ml test tube and then carefully reduce to 1 ml under a gentle stream of nitrogen at ambient temperature. Transfer the concentrated extract to a 2-ml vial and crimp.

NOTE 1 It should be avoided evaporating the ether extract to dryness as this has been shown to adversely affect amine recovery.

NOTE 2 The recovery of amines can be improved by converting them to their hydrochloride salts.

Analyse the extract in accordance with 5.4 of EN 71-11:2005.

8.9.3 Preservatives

Obtain *test portions* of the *laboratory sample* in the same way as detailed in 8.9.1.

Weigh, to the nearest 1 mg, approximately 1,0 g of the *test portion* into a 50-ml polypropylene tube. Add 15 ml water (6.1) and agitate on a Vortex[®] mixer for 30 s. Pour the liquid into a suitable container.

Analyse the extract in accordance with 5.7 of EN 71-11:2005; 5.5.2 of EN 71-11:2005, the method for phenol; and the method in the relevant EU Directive for the identification and determination of free formaldehyde in cosmetic products.

NOTE Commission Directive 90/207/EEC refers.

⁴ SPE column Chromabond XTR, 70 ml, 14,5 g, is an example of a suitable product available commercially. This information is given for the convenience of users of this European Standard and does not constitute an endorsement by CEN.

Annex A (normative)

First-action method for colourants and primary aromatic amines

A.1 Principle

The test fabric is placed adjacent to a multifibre fabric and wetted in either acidic or alkaline sweat. The *test portion* is placed between two acrylic plates under a specified pressure in a test device for 4 h at (37 ± 2) °C. The multifibre fabric is then dried in air and assessed for colour staining.

A.2 Test apparatus and reagents

A.2.1 Test device

A perspirometer consisting of a stainless steel frame into which a weight-piece with a mass of approximately 5 kg and a base of (60 x 155) mm is closely fitted, so that a pressure of 12,5 kPa can be applied on test specimens measuring (40 x 100) mm placed between acrylic sheets measuring (60 x 115 x 1,5) mm. The test device can be designed so that if the weight-piece is removed during the test the pressure of 12,5 kPa remains unchanged.

A.2.2 Oven

Non-circulating type capable of maintaining a temperature of (37 ± 2) °C

A.2.3 Test solution 1

Dissolve 0,5 g L-histidine monohydrochloride monohydrate, 5,0 g sodium chloride and 2,5 g disodium hydrogen orthophosphate dihydrate in approximately 980 ml deionized, or equivalent, water. Adjust the pH to $8,0 \pm 0,1$ with 0,1 mol/l sodium hydroxide solution and make up to 1 000 ml with water.

A.2.4 Test solution 2

Dissolve 0,5 g L-histidine monohydrochloride monohydrate, 5,0 g sodium chloride and 2,2 g sodium dihydrogen orthophosphate dihydrate in approximately 980 ml deionized, or equivalent, water. Adjust the pH to $5,5 \pm 0,1$ with 0,1 mol/l sodium hydroxide solution and make up to 1 000 ml with water.

A.2.5 Adjacent fabric

Multifibre adjacent fabric type DW complying with ISO 105-F10. This fabric comprises segments of the following materials: cellulose acetate, cotton, polyamide, polyester, acrylic and wool.

A.3 Procedure

Treat each colour as a separate sample.

Examine the *laboratory sample* and determine which textile components are present and *accessible*.

Cut *test portions* of (40 x 100) mm from *accessible* textile components. If the *laboratory sample* is not this size, then cut the *test portion* so that a representative section of the *test portion* covers each of the segments of the multifibre adjacent fabric.

NOTE The aim is to cover each segment of the multifibre fabric with a representative portion of the *laboratory sample*.

Obtain two test pieces of each *accessible* component, one for each of the test solutions.

Secure the test piece to the adjacent fabric (A.2.5) using untreated cotton by sewing along one of the shorter edges to form a composite test piece.

Place the composite test pieces in the test solution for 30 min, one in test solution 1 (A.2.3) and one in test solution 2 (A.2.4), ensuring that the liquor has penetrated the composite test piece. After 30 min, remove the composite test pieces and the excess solution from them with the aid of two glass rods.

Place the composite test pieces between two of the acrylic plates in the preheated test device, and apply a pressure of 12,5 kPa. Place the test device in the oven (A.2.2) for 4 h at $(37 \pm 2) ^\circ\text{C}$. Each test solution requires a separate test device.

After 4 h remove each composite test piece sample, open and allow to air dry.

Examine the multifibre adjacent fabric for evidence of colour staining.

A.4 Evaluation

A textile sample is deemed to be colourfast if there is no colour staining or staining equivalent to a change in colour of the multifibre adjacent fabric of less than 3 to 4 on the Grey scale as defined in EN 20105-A03.

Annex B (informative)

Rationale

B.1 Scope

When considering how children might be exposed to the organic compounds in toys, all potential contact routes were considered, i.e. oral, ingestion, skin contact, eye contact, inhalation and mucous membrane contact.

These contact routes were identified in a mandate given to CEN (M/229) by the European Commission.

Each contact route was considered at length and the associated exposure, analytical problems and toxicological significances were prioritised in order to create a manageable European Standard for surveillance authorities and industry.

B.2 Accessible (see 3.1)

The organic compounds within parts of toys that are not accessible are not of toxicological concern. This definition is therefore designed to exclude those parts from certain requirements of EN 71-9.

B.3 First-action method (see 3.3)

Methods are provided within this European Standard, which are designed to show compliance with EN 71-9. Since they are non-specific methods, which do not determine individual organic compounds quantitatively, they may not be used to show non-compliance.

B.4 Laboratory sample (see 3.5)

A laboratory sample is one toy. The limits within EN 71-9 and the sampling procedures within this European Standard take into account the exposure of children from specific amounts of toy material. The limits will not apply to samples created by collecting material from more than one toy.

B.5 Mouthed (see 3.7)

The limits in EN 71-9 have been calculated based on long-term licking, sucking and chewing of toys that are intended or likely to be mouthed for a significant time. Examples are teethingers, rattles and other hand-held soft plastic toys for young children.

B.6 Requirements (see Clause 4)

Table 1 specifies which clauses of this European Standard are to be followed to determine compliance or non-compliance with EN 71-9; that is, the procedure by which toy materials should be prepared and extracted.

First-action methods are provided in some cases, which are designed to show that a particular organic compound or group of compounds is not present in any significant quantity compared with the maximum limits. Since the first-action method for colourants and primary aromatic amines is non-specific and does not

determine individual organic compounds quantitatively and the first-action method for inhalation of solvents and monomers is not representative of real-life exposure, they may not be used to demonstrate non-compliance.

B.7 Simulant (see 6.1)

Analytical trials have shown, for the organic compounds of interest, that water was as good a simulant as others commonly used in migration analysis. The migration into water was shown to be suitable to represent all contact routes (except inhalation).

On this basis it was decided to use only water as the migration simulant and that this one migration procedure could be used to assess all contact routes except inhalation.

B.8 Extraction (see 6.4)

The head-over-heels method is based on a procedure that has been validated for the extraction of phthalate plasticisers to address the opinion of the EC Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on the validation of methodologies for the release of di-isononyl phthalate in saliva simulant from toys. A sample size of 10 cm² was chosen to represent the maximum area of an object easily mouthed by a small child. Since the amount of saliva produced by a child is not proportional to the size of object placed in the mouth, no reduction in simulant volume is permitted if objects smaller than 10 cm² are tested.

B.9 Methods of analysis

The majority of the methods used to assess toys against the requirements of EN 71-9 are those defined in EN 71-11. These methods are used in conjunction with the sample preparation and extraction conditions specified in this European Standard, and are designed to approximate to real exposure conditions or give equivalent results.

In some cases, first-action methods are provided that are designed to show that a particular organic compound or group of compounds is not present in any significant quantity compared with the maximum limits.

Some of the methods described in this European Standard are capable of determining organic compounds for which limits are not specified in EN 71-9. Future revisions of EN 71-9 may assign limits to these compounds. The methods have been developed with this in mind.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 88/378/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 88/378/EEC.

Once this European Standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this European Standard given in Table ZA.1 confers, within the limits of the scope of this European Standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 – Correspondence between this European Standard and Directive 88/378/EEC

| Corresponding requirement clauses of this standard | Requirements of Directive 88/378/EEC |
|----------------------------------------------------|--------------------------------------|
| ANNEX II. 3. 1 Chemical properties | Clause 4 |
| ANNEX II. 3. 3 Chemical properties | Clause 4 |

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this European Standard.

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