EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 14372

August 2004

ICS 97.190

English version

Child use and care articles - Cutlery and feeding utensils - Safety requirements and tests

Articles de puériculture - Couverts et vaisselle - Exigences de sécurité et essais

Artikel für Säuglinge und Kleinkinder - Besteck und Geschirr - Sicherheitstechnische Anforderungen und Prüfungen

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

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Ref. No. EN 14372:2004: E

Contents

Foreword

This document (EN 14372:2004) 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of an identical text or by endorsement, at the latest by February 2005, and conflicting national standards shall be withdrawn at the latest by February 2005.

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 the United Kingdom.

Introduction

This document establishes minimum safety requirements and specifies appropriate test methods for children's cutlery and feeding utensils. Children's cutlery and feeding utensils are used by either the carer to feed the child or by the child itself, from the average age of weaning (6 months) to 3 years of age. Children over three years of age increasingly use cutlery and utensils designed for adults. Accordingly, this document addresses the potential hazard(s) arising from the use of cutlery and feeding utensils designed for the use of children aged up to 3 years, with or without parental supervision.

However, it is stressed that this document cannot eliminate all possible risks to young children up to 3 years of age using such products and that parental or guardian control is of paramount importance.

It is essential that the manufacturer gives all warnings and instructions specified in this document clearly, to allow the consumer to ensure the product is used correctly and safely.

A significant choking hazard can arise if components of cutlery or feeding utensils become separated during use. This hazard is addressed in this document by the inclusion of security tests.

This document also addresses the potential hazard(s) arising from the release of one or more substances, in quantities which could be considered detrimental to health, from the material(s), used in the construction of cutlery and feeding utensils.

It is noted that all plastic components of cutlery and feeding utensils are regulated by the Commission Directive 2002/72/EC [1] relating to plastics materials and articles intended to come into contact with foodstuff.

It is further noted that Council Directive 89/109/EEC [2] approximates laws of the Member States relating to materials and articles intended to come into contact with foodstuff. Where applicable, Council Directive 82/711/EEC [3] and related amendments (93/8/EEC and 97/48/EC) laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuff has been applied as has Council Directive 85/572/EEC [4] relating to the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuff.

It is also noted that the European Parliament and Council Directive 94/27/EC [5] regulates nickel release permitted from jewellery and items in contact with the skin.

It is noted that Council Directive 84/500/EEC [6] relates to ceramic articles intended to come into contact with foodstuff.

Commission Decision 99/815/EC [7] prohibits the placing on the market of toys and childcare articles made of soft PVC (containing one or more of six specific phthalate plasticisers) and which are intended to be placed in the mouth by children under three years of age.

It is recommended that manufacturers and suppliers operate to EN ISO 9001 [8] standard for quality management systems.

1 Scope

This document specifies safety requirements relating to the materials, construction, performance, packaging and labelling of cutlery and feeding utensils. All products which are intended to be used by a child aged up to 36 months to eat by itself or with the assistance of another person are included in the scope of this document. This includes products which have a different primary function, but have a secondary function intended to allow a child to use the product to eat by itself or with the assistance of another person.

It does not apply to pre-prepared food containers, or to cutlery and feeding utensils designed for specialist medical applications or for use under medical supervision.

It includes test methods for the mechanical and chemical requirements specified and requirements relating to the instructions of use.

There are some products designed as a toy or with features that resemble a toy. These products shall additionally meet the relevant requirements of EN 71.

This document is not applicable for drinking equipment (feeding bottles, teats, spouts, and cups) which is covered by EN 14350-1 and EN 14350-2.

2 Normative references

The following referenced documents are indispensable for the application of this document. 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 71-3, *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 ISO 2409, *Paints and varnishes - Cross-cut test (ISO 2409:1992)*

EN ISO 4614, *Plastics - Melamine-formaldehyde mouldings - Determination of extractable formaldehyde (ISO 4614:1977).*

3 Terms and definitions

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

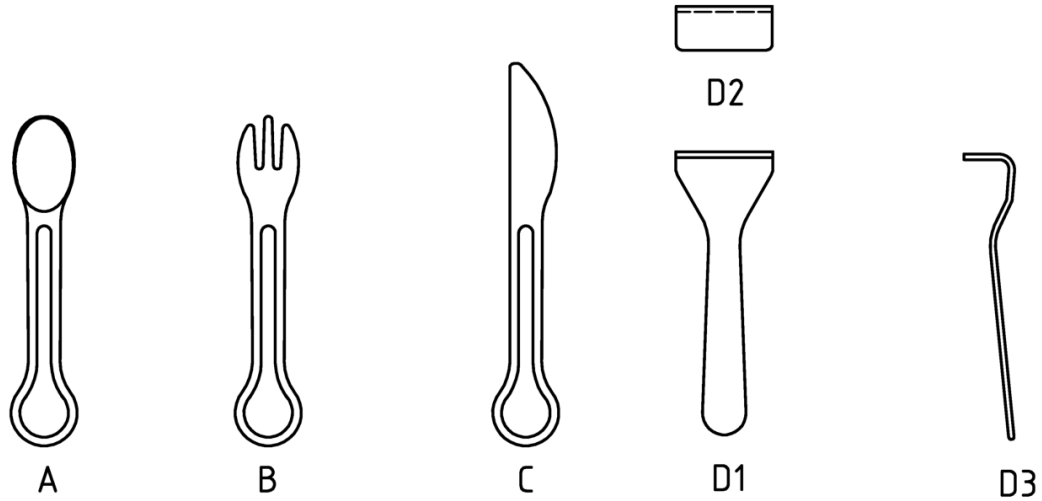
3.1
cutlery
implements used for eating such as knives, forks, spoons and food pushers

3.2
feeding utensils
implements or containers used for feeding children such as plates and bowls

3.3
suction pad
component of a feeding utensil intended to adhere or secure the utensil to a surface

4 Examples of cutlery and feeding utensils

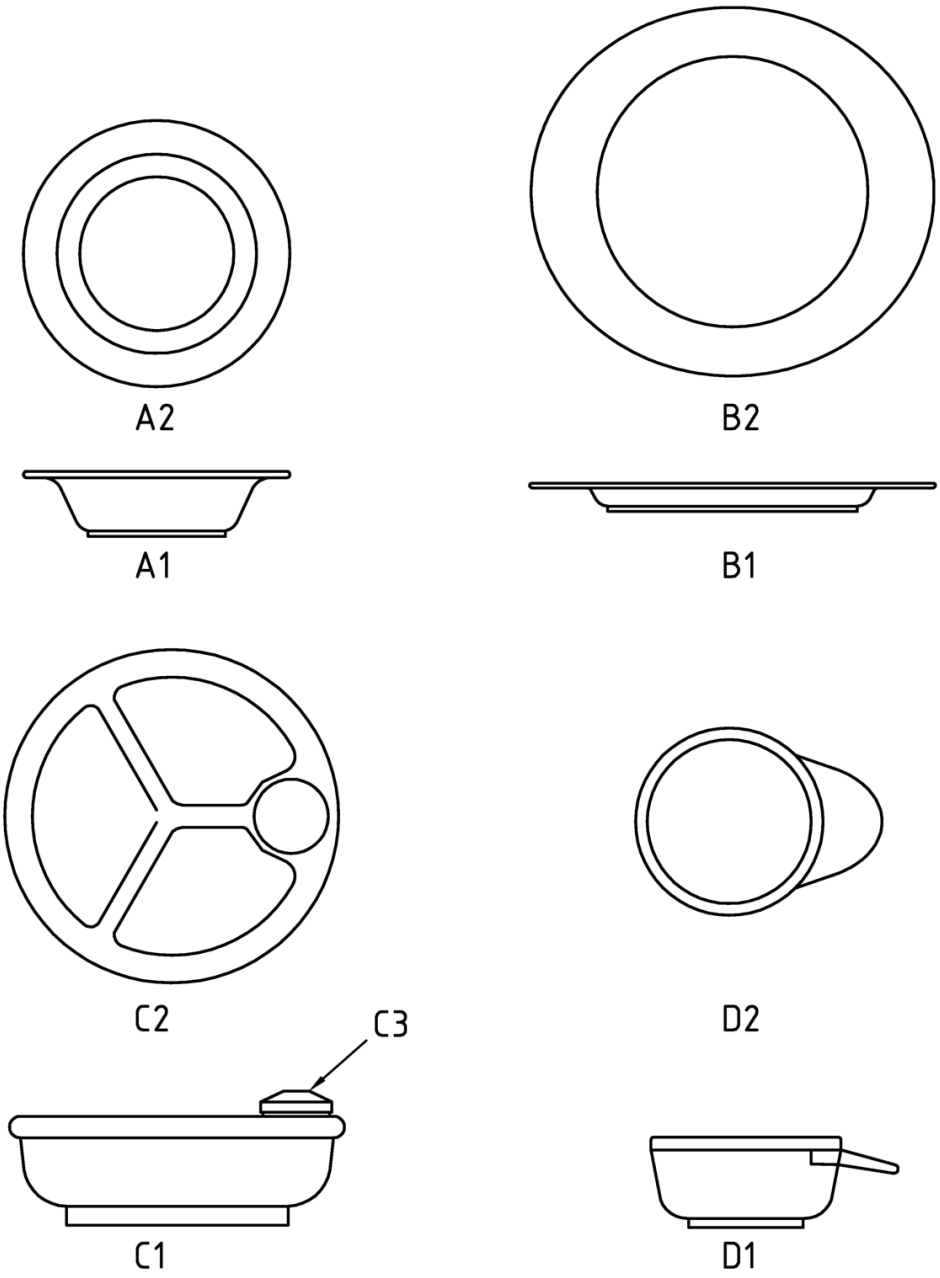
Examples of cutlery and feeding utensils are shown in Figures 1, 2 and 3.



Key

A Spoon
B Fork
C Knife
D1 Food pusher – top view
D2 Food pusher – front view
D3 Food pusher – side view

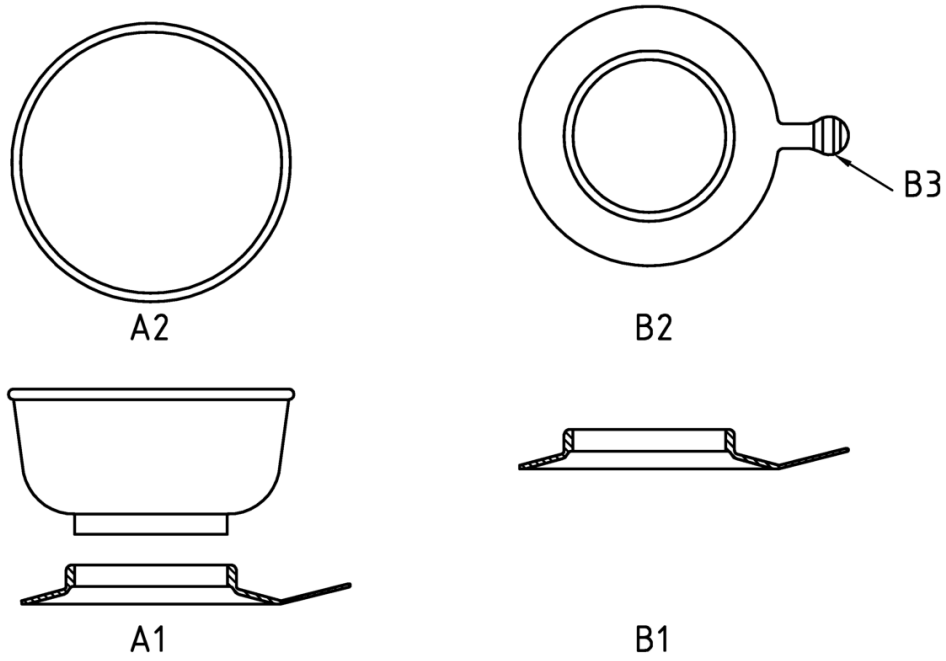
Figure 1 — Examples of cutlery



Key

A 1 Bowl – side view
A 2 Bowl – top view
B 1 Plate – side view
B 2 Plate – top view
C 1 Keep-warm plate – side view
C 2 Keep-warm plate – top view
C 3 Removable plug on keep-warm plate
D 1 Weaning bowl – side view
D 2 Weaning bowl – top view

Figure 2 — Examples of feeding utensils



Key

A 1 Feeding utensil with suction pad – side view
A 2 Feeding utensil – top view
B 1 Suction pad – side view
B 2 Suction pad – top view
B 3 Suction pad release tab

Figure 3 — Example of a feeding utensil with separate suction pad

5 Requirements

5.1 General

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

5.2 General requirements

5.2.1 Visual and tactile examination

All components of cutlery and feeding utensils when assembled for use, shall be free from points and edges which are likely to cause injury. The article shall be free from splinters, burrs and flash.

5.2.2 Sharp points

Accessible points shall not be sharp points as determined in accordance with 6.2.1.

5.2.3 Sharp edges

Accessible edges shall not be sharp edges as determined in accordance with 6.2.2.

5.2.4 Small parts

When inserted into a small parts cylinder (see Figure 4), no component part of tested sample shall fit entirely within the cylinder in any orientation and without compression.

Dimensions in millimetres

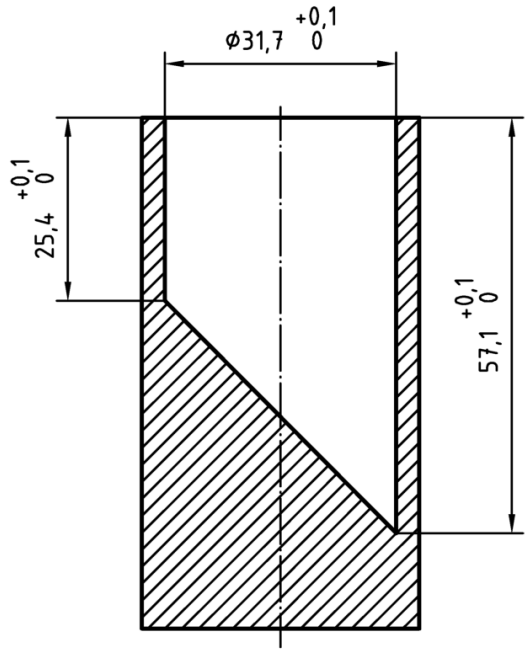


Figure 4 — Small parts cylinder

5.2.5 Holes (Finger traps)

To avoid entrapment of fingers there shall be no accessible hole which allows the insertion of a 5,5 mm diameter rod, unless the accessible hole also allows the insertion of a 12 mm diameter rod or has a penetration of less than 10 mm.

This requirement applies only to components made of materials with a Shore A hardness of more than 60 IRHDs.

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

5.2.6 Printed decorations

When tested in accordance with EN ISO 2409, no print from decoration shall be removed from any product.

Adhesive labels shall not be used.

5.3 Mechanical requirements

5.3.1 Tensile strength

All products with more than one component and which are intended to be held by a child shall be tested as described in 6.2.3. No component shall break, tear or separate during this test.

5.3.2 Torque test

If a component can be gripped between thumb and forefinger, it shall be torque tested according to EN 71-1. No component shall break, tear or separate during this test.

5.3.3 Tear resistance

Components produced out of materials with a Shore A hardness of less than 60 IRHDs but excluding suction pads shall be tested as described in 6.2.4. The tested component shall not break, tear or separate during the subsequent tensile test.

5.3.4 Strength/rigidity

When tested in accordance with 6.2.5, no component of cutlery shall break, tear or separate.

5.3.5 Drop test

All products shall be tested in accordance with EN 71-1. If the product breaks, a warning shall be provided as given in 7.4.

5.4 Chemical requirements

5.4.1 General

Materials used for the manufacture of cutlery and feeding utensils shall be subjected to the tests listed in Table 1 and shall conform to 5.4.2.

5.4.2 Chemical properties

5.4.2.1 Requirements by material

Materials used in the manufacture of components of cutlery and feeding utensils shall be subjected to the tests marked with an x in Table 1.

Table 1 — Tests to be carried out on materials

Material	Tests					
	Migration of certain elements (see 6.3.1)	Phthalate content (see 6.3.2)	Volatile compounds content (see 6.3.3)	Formaldehyde release (see 6.3.4)	Nickel release (see 6.3.5)	Bisphenol A release (see 6.3.6)
Silicone rubber	x		x			
Thermoplastic elastomers (TPEs)	x					
Glass, ceramics, glass-ceramics, vitreous enamels and other enamels	x					
Thermoplastics	x	x				x [a]
Thermosetting plastics	x			x		
Metals / Alloys	x				x	
Wood	x			x		
[a] Only thermoplastics containing polycarbonate or polysulfone shall be tested for Bisphenol A release						

5.4.2.2 Migration of certain elements

When tested in accordance with 6.3.1, the migration of all elements from all material(s) used in the manufacture of cutlery and feeding utensils shall not exceed the limits given in Table 2.

When components of cutlery and feeding utensils are manufactured of different material(s), or in different colours, all components shall be tested individually. Decorations shall be considered to be part(s) of the material(s) on which they are printed.

Table 2 — Limits of element migration

Element	Limit mg/kg
Antimony, Sb	15
Arsenic, As	10
Barium, Ba	100
Cadmium, Cd	20
Lead, Pb	25
Chromium, Cr	10
Mercury, Hg	10
Selenium, Se	100
NOTE The analytical method specified in EN 71-3 has been applied in this document to cutlery and feeding utensils. The limits have been set based on the limit of detection for each element using commonly available analytical techniques.	

5.4.2.3 Phthalate content

When thermoplastic components of cutlery and feeding utensils are tested according to 6.3.2, the total content of specified phthalates shall not exceed 0,1 % (m/m).

5.4.2.4 Volatile compounds content

When silicone rubber components of cutlery and feeding utensils are tested according to 6.3.3, the volatile compounds content shall not exceed 0,5 % (m/m).

5.4.2.5 Formaldehyde release

When thermosetting plastic or wood components of cutlery and feeding utensils are tested according to 6.3.4, the release of formaldehyde shall not exceed 15 mg formaldehyde/kg migration liquid.

5.4.2.6 Nickel release

When metal or alloys are tested according to 6.3.5, the release of nickel shall not exceed 0,5 µg/cm^2/week.

5.4.2.7 2,2-bis(4-hydroxyphenyl)propane [Bisphenol A] (BPA) release

When polycarbonate and polysulfone containing thermoplastic components of cutlery and feeding utensils are tested according to 6.3.6, the migration of the following chemical shall not exceed 0,03 µg/ml into aqueous food simulant:

2,2-bis(4-hydroxyphenyl)propane [Bisphenol A] (BPA)

CAS No. 80-05-7

IUPAC 4,4'-(methylethylidene)-bisphenol or 4,4'-isopropylidenediphenol

6 Test methods

6.1 Preparation of samples and general testing conditions

All samples shall be submerged in water at (60 ± 2) °C for (10 ± 0,5) min. Drain excess water before allowing the samples to cool to room temperature in a desiccator for (24 ± 1) h prior to testing. Use new samples, preferably from the same batch, for each test unless otherwise stated (i.e. samples used in one test shall not be used in another test).

6.2 Mechanical tests

6.2.1 Sharp points test

Test in accordance with EN 71-1.

6.2.2 Sharp edges test

Test in accordance with EN 71-1.

6.2.3 Tensile test

The tensile force shall be applied to one component of the sample whilst another component is firmly held. A pre-load of (5 ± 2) N shall be applied to align the specimen and then the force shall be increased to (90 ± 5) N at a cross head speed of (10 ± 5) mm/min and maintained at that level for (10 ± 1) s.

Clamps or other devices shall hold the components securely during the test without giving rise to damage which might affect the test result. Any results where such damage occurs shall be disregarded.

Tests shall be carried out along the major axis and at the right angles to the major axis. Every possible combination of pairs of components shall be tested.

6.2.4 Tear resistance test

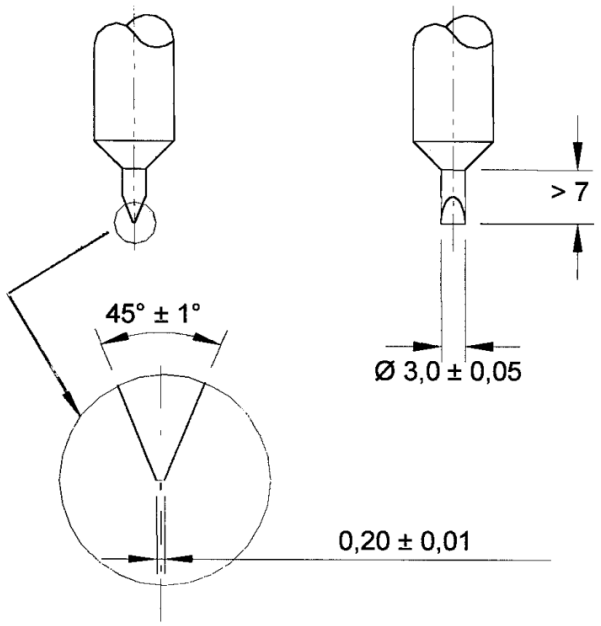
The components to be tested shall be separated or if necessary, cut from any other components.

Place the component to be tested on a cutting board of at least 10 mm thickness and (70 ± 5) Shore D hardness. Place the tip of the indentor, the shape and dimensions of which are given in Figure 5, in the approximate centre of the largest surface of the component to be tested.

At a crosshead speed of (10 ± 5) mm/min apply a force of (200 ± 10) N for (1 ± 0,5) s.

If the indentor punctures the component carry out a tensile test in accordance with 6.2.3. For the component suitable fixing devices shall be used to hold opposite ends of the component securely, so that the puncture produced by the indentor is at 90 ° to the axis of tensile force.

Dimensions in millimetres



NOTE 1 All dimensions with a tolerance are machined as EN ISO 1302 [9] to Ra 0,4

NOTE 2 Material: H13 high chrome tool steel or equivalent. Harden to 45-50 Rockwell C

Figure 5 — Indentor for tear resistance test

6.2.5 Strength/rigidity

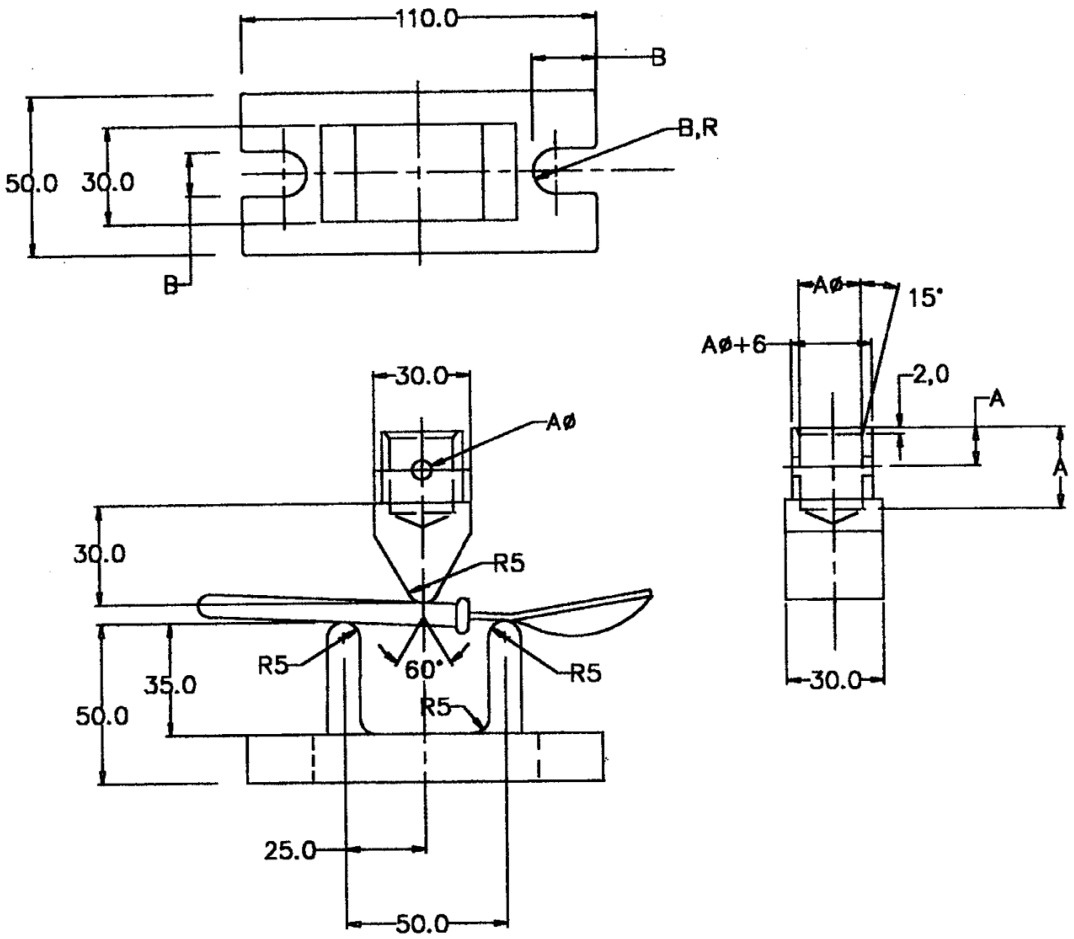
The test shall be applied to all cutlery.

A tensile testing machine with an attachment to facilitate three-point bend loading onto handles of articles shall be used to apply a compression load to (100 ± 5) N at a crosshead speed of (10 ± 5) mm/min and maintain for (10 ± 1) s as shown in Figure 6.

The load shall be applied at the mid point of item's length. The test shall be repeated with load applied at (30 ± 1) mm either end of the product. In each test the restraining points shall be positioned (25 ± 1) mm from the load point.

Note It may be necessary to prevent the cutlery from slipping during the test.

Dimensions in millimetres



NOTE 1 Material: H13 high chrome tool steel or equivalent. Harden to 45-50 Rockwell C.

NOTE 2 Dimensions marked as "A" made to fit the individual test machine load cell.

NOTE 3 Dimensions marked as "B" made to fit the individual test machine table.

Figure 6 — Apparatus for strength/rigidity test

6.3 Chemical tests

6.3.1 Determination of the migration of certain elements

6.3.1.1 Principle

Soluble elements (antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium) are extracted from the individual components of the cutlery and feeding utensils which are accessible to the child. Conditions which simulate contact with stomach acid shall be used. The concentrations of the soluble elements are described quantitatively.

6.3.1.2 Apparatus, reagents, procedure and determination

Tests shall be carried out according to EN 71-3.

6.3.2 Determination of phthalate content

6.3.2.1 Principle

The aim of the method is primarily to extract, identify and quantify monomeric phthalates (with wider application to other types of plasticisers) contained in PVC samples. The extraction method uses Soxhlet extraction apparatus with diethyl ether. The total diethyl ether extractable plasticiser content is calculated by weight with Gas Chromatography-Mass Spectroscopy (GC-MS) detection to identify and quantify individual phthalates.

NOTE It is recommended that suitable qualitative methods be used to identify chlorine containing materials [10].

6.3.2.2 Apparatus

6.3.2.2.1 Balance (accurate to 4 decimal points).

6.3.2.2.2 150 ml stoppered flat-bottomed flask.

6.3.2.2.3 Soxhlet extractor with siphon cup.

6.3.2.2.4 Soxhlet cellulose thimble.

6.3.2.2.5 Water cooled condenser.

6.3.2.2.6 Spark proof heating mantle/water bath.

6.3.2.2.7 Steam bath.

6.3.2.2.8 Oven (105 ± 5) °C.

6.3.2.2.9 Desiccator chamber.

6.3.2.2.10 (200 ± 0,15) ml volumetric flask.

6.3.2.3 Reagents (analytical grade)

6.3.2.3.1 Diethyl ether.

6.3.2.3.2 n-Hexane.

6.3.2.3.3 Di-isononyl phthalate (DINP), CAS No. 28553-12-0.

6.3.2.3.4 Di-(2-ethylhexyl) phthalate (DEHP), CAS No. 117-81-7.

6.3.2.3.5 Di-n-octyl phthalate (DNOP), CAS No. 117-84-0.

6.3.2.3.6 Di-iso-decyl phthalate (DIDP), CAS No. 26761-40-0.

6.3.2.3.7 Butyl benzyl phthalate (BBP), CAS No. 85-68-7.

6.3.2.3.8 Di-butyl phthalate (DBP), CAS No. 84-74-2.

6.3.2.4 Reagents (standard solutions)

Prepare a series of individual stock standard solutions of the individual phthalate esters in n-Hexane as shown in Table 3.

Table 3 — Stock solutions

Phthalate ester	DIDP	DINP	DBP	BBP	DNOP	DEHP
Concentration µg/ml	5 000	5 000	200	200	200	200

Where appropriate from the stock standard solutions prepare two sets of five phthalate esters GC-MS calibration solutions in n-Hexane to the maximum linear concentration shown in Table 4 (Calibration Set 1), and Table 5 (Calibration Set 2).

Table 4 — Calibration Set 1

Phthalate ester	DINP	DBP	BBP	DEHP
Concentration µg/ml	5 000	20	20	20

Table 5 — Calibration Set 2

Phthalate ester	DIDP	DNOP
Concentration µg/ml	5 000	20

6.3.2.5 Sampling, extraction and gravimetric analysis for phthalate plasticisers

Place the sample in a pre-weighed 150 ml flat bottomed flask and heat in an oven at (105 ± 5) °C for (30 ± 5) min. Allow to cool in a desiccator. Weigh the flask and sample. Use a scalpel or other appropriate cutting utensils to cut a representative portion from the sample into small pieces (< 5 mm ∅). Weigh accurately (2 ± 0,2) g of the pieces into a Soxhlet thimble and add cotton wool to the top of the thimble.

Add approximately (50 ± 10) ml of diethyl ether into the flask. Reflux gently for 6 h ± 30 min. Allow sufficient time for the diethyl ether to cool. Completely evaporate the diethyl ether by means of a steam bath. Place the flask in an oven at (105 ± 5) °C for (30 ± 5) min. Allow to cool in a desiccator and weigh. Repeat the drying and cooling cycles until the difference between two consecutive weighings are not more than 0,0005 g. A blank solution shall be run consecutively.

6.3.2.6 Preparation of sample extract solution for Gas Chromatography-Mass Spectroscopy (GC-MS)

To the weighed extract (6.3.2.5) add (50 ± 2) ml of n-Hexane. Stopper the flask and swirl to completely dissolve the extract. Decant the solution into a 200 ml volumetric flask, repeatedly rinsing the flask with n-hexane. Make up to the mark. Prepare (if necessary) further diluted solutions using n-hexane such that the final concentration in solution is within the linear calibration concentration for phthalate present. Transfer a portion of the n-hexane solution into a capped vial for GC-MS analysis.

Suitable GC-MS column and method and data on the repeatability of the method are described in Annex A.

6.3.2.7 Calculation of results

Compare the obtained GC-MS spectra to known spectra or phthalate ester standards to allow qualitative identification of phthalate ester plasticisers or any other compounds. Plot a calibration graph of the response against the known standard concentrations.

From the calibration graph determine the response of phthalate ester found in the blank/sample and interpolate the concentration of phthalate ester in µg/ml correcting for any dilutions.

Gravimetric analysis

$$\% \text{ Extract (m/m)} = \frac{\text{Weight of extract (g)}}{\text{Weight of sample (g)}} \times 100$$

GC-MS analysis

$$\% \text{ Plasticiser (m/m)} = \frac{\text{Extract solution (µg/ml)} \times 200 \text{ (ml)}}{\text{Weight of sample (g)} \times 10\,000} \times \text{dilution factor}$$

6.3.3 Determination of volatile compounds content

6.3.3.1 Procedure

All weighings shall be with an accuracy of at least ± 0,1 mg.

Drain excess water from the sample preparation stage (see 6.1).

Pre-heat an open, shallow container for 1 h at (100 ± 5) °C. Cool the container in a desiccator for 1 h and weigh (weight a).

Place approximately 10 g of the whole sample into the container and place in a drying oven at (100 ± 5) °C with fresh air inlet. After 1 h, cool the container and sample in a desiccator for at least 2 h and weigh (weight b).

Replace the container with the sample in a drying oven at (200 ± 5) °C with fresh air inlet. After 4 h, cool the container and sample in a desiccator for at least 2 h and re-weigh (weight c.)

The volatile compounds content is calculated from the percentage weight difference between weight b and weight c, after deducting the weight of the container (weight a).

6.3.4 Determination of formaldehyde release

The levels of formaldehyde release from cutlery and feeding utensils shall be determined using the method outlined in EN ISO 4614.

6.3.5 Determination of nickel release

All metal and alloy components shall be tested according to EN 1811.

6.3.6 Determination of 2,2-bis(4-hydroxyphenyl)propane [Bisphenol A] (BPA) release

6.3.6.1 Principle

BPA is extracted from the test articles into aqueous food simulant, identified and its level determined by high performance liquid chromatography (HPLC) with ultra violet diode array detection (UV-DAD) and fluorescence detection (FLD). [1)]

NOTE 1 UV-DAD without FLD is only applicable for concentrations of BPA in excess of 0,1 µg/ml.

1) This method is partially based on prEN 13130-13 [11]

NOTE 2 Alternative methodology, such as gas chromatography (GC), has been documented and may be used. However, in comparison with the gas chromatographic method, the HPLC method has the advantage that Bisphenol A can be determined directly in the migrate without pre-concentration and derivatisation.

6.3.6.2 Apparatus

6.3.6.2.1 HPLC preferably equipped with an automatic 50 µl loop injector and a variable wavelength UV-DAD, fluorescence detector and data station.

6.3.6.2.2 HPLC column capable of separating BPA fully from peaks originating from simulants and/or solvents used.

6.3.6.2.3 Membrane filter with a pore size of 0,45 µm.

6.3.6.2.4 Analytical balance with sensitivity of 0,0001 g.

6.3.6.2.5 Micro syringes: 10 µl, 20 µl and 50 µl.

6.3.6.3 Reagents: chemicals (analytical reagent grade unless otherwise specified)

6.3.6.3.1 Water (HPLC grade).

6.3.6.3.2 Methanol (HPLC grade).

6.3.6.3.3 Distilled water.

6.3.6.4 Reagents: authentic samples (purity greater than 98 %)

6.3.6.4.1 2,2-bis(4-hydroxyphenyl)propane [Bisphenol A] (BPA).

6.3.6.5 Reagents: standard solutions

6.3.6.5.1 Stock standard solution of BPA in methanol at defined concentration of approx. 1,0 mg/ml.

Weigh to the nearest 0,1 mg approx. 100 mg BPA (6.3.6.4.1) into a 100 ml volumetric flask. Dissolve the BPA in methanol (6.3.6.3.2) and make up to the mark with methanol.

Calculate the concentration in µg BPA/ml solution.

Repeat the procedure to obtain a second stock solution.

NOTE The solution may be stored refrigerated at +4 °C in a closed container, free from light for a period of at least 3 weeks.

6.3.6.5.2 Calibration solutions

Transfer by micro syringe 0 µl, 10,0 µl, 20,0 µl, 30,0 µl, 40,0 µl, 50,0 µl of the stock standard solution (6.3.6.5.1) into a series of six 1 000 ml volumetric flasks and make up to the mark with analyte-free aqueous food simulant (6.3.6.3.3) and mix thoroughly.

Calculate the exact concentrations of BPA in the calibration samples in µg/ml.

Repeat the procedure using the second stock solution (6.3.6.5.1).

6.3.6.6 Procedure

For feeding utensils, transfer 100 ml of the aqueous food simulant (6.3.6.3.3) into the test article. If this volume is too large, then use a known volume equivalent to 50 % of the capacity of the utensils. For cutlery, place the test article in a 200 ml measuring cylinder (or equivalent) and add a known volume of aqueous food simulant (6.3.6.3.3)

sufficient to just cover the article. Store under static conditions for 24 h at 40 °C in a drying oven before transferring approximately 1 ml of the solution into a vial suitable for HPLC injection.

If storage is necessary, sample solutions shall be refrigerated at +4 °C in closed containers, free from light.

6.3.6.7 Determination of the quantity of migrated BPA

Inject the calibration solutions (6.3.6.5.2) into a HPLC (6.3.6.2.1) with HPLC column (6.3.6.2.2). Produce calibration curves of µg BPA/ml food simulant using the twelve values from the two stock solutions.

NOTE The calibration curve should be rectilinear and the correlation coefficient 0,997 or better. The two sets of calibration solutions made from independently prepared stock solutions should be cross-checked by generating two calibration curves which, on the basis of peak ratio measurement, should agree to ± 5 % of one another.

Inject the test sample solutions (6.3.6.6) into the HPLC. Use the calibration curve to determine the BPA-content of the test solution, either manually or with data-handling software. A detection limit of ≤ 20 µg BPA/l aqueous simulant solution (0,02 µg BPA/ml) shall be obtained.

NOTE 1 A suitable HPLC apparatus and method are described in Annex B.

NOTE 2 It is recommended that the test be carried out at least in duplicate.

7 Product information

7.1 General

The text shall be printed in the official languages of the country of retail sale. If other languages are included, they shall be easy to distinguish, e.g. by separate presentation.

The text shall be clearly legible. Sentences shall be short and of simple construction. The words used shall be uncomplicated and in everyday use.

NOTE It is recommended that products or the packaging be batch coded.

7.2 Purchase information

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

NOTE Some examples are: on the packaging; on a leaflet placed inside the product but which is visible at the point of sale; printed on the side of the product.

1) name, trademark or other means 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) number of this document, but not year;

3) recommended age range for using the product;

4) instructions for use given in 7.3, or if these are included in a leaflet within the packaging, a note indicating that this is the case.

7.3 Instruction for use

The following information shall be provided on the product, packaging or information leaflet:

1) information for the safe use of the product;

2) at least one method of cleaning;

3) before first use, clean the product;

4) unsuitable common methods of storage, cleaning and use which might damage the product (e.g. microwaves, sunlight, dishwasher detergent);

5) if the product can be used for heating food, unsuitable methods of heating.

7.4 Warnings

The following warnings shall be provided on the product, packaging or information leaflet:

For your child's safety and health

Warning!

Always use this product with adult supervision.

Before each use, inspect the product. Throw away at the first sign of damage or weakness.

If the product fails requirement 5.3.5, the following warning shall be provided in the form given:

This product may break if dropped

Always check food temperature before feeding.

If the product is designed to contain a liquid used to heat the food, a warning indicating the possible dangers to the child shall be provided

Annex A
(informative)

Suitable Gas Chromatography–Mass Spectrometry (GC-MS) apparatus, method and precision data for determination of phthalate plasticisers

The following equipment, column and operating conditions have been found suitable: Model: 5890 Gas Chromatograph (GC) with a Hewlett Packard 5971A Mass Selective Device (MSD) with scan range 50 - 500 atomic mass unit, and column 30 meters, 0,25 mm I.D. & 0,15 µm film thickness, 50 % dimethyl-50 % diphenyl-polysiloxane, e.g. DB-17HT.

Carrier gas:	Helium.
Flow rate:	0,8 ml/min.
Injector temperature:	290 °C.
Injection volume:	2 µl.
Injection typ:	splitless.
Detector:	MSD.
Transfer line temperature:	280 °C.
MSD mode:	Electron impact.
Temperature programme:	40 °C for 4 min.

From 40 °C to 300 °C at 10 °C/min.

Isothermal 4,00 min.

Total run time is 34 min.

Typical quantitation ions for phthalate plasticisers are shown in Table A.1.

Table A.1 — Typical quantitation ions for phthalate plasticisers

Phthalate plasticisers	Tgt ion	Q1	Q2	Q3
Dibutyl phthalate (DBP)	149	223	278	
Butyl benzyl phthalate (BBP)	149	206	238	
Bis-(2-ethylhexyl) phthalate (DEHP)	149	167	279	
Di-n-octyl phthalate (DNOP)	149	279	261	
Di-isononyl phthalate (DINP)	149	293	127	167
Di-isodecyl phthalate (DIDP)	149	307	167	141

Depending on the type of equipment used, the appropriate operating conditions may need to be established.

Detection limits and precision data

Total plasticiser content by gravimetry:

The detection limit for total plasticiser content by gravimetry is 0,05 % (m/m).

The repeatability (*r*) data on 6 analyses of a PVC reference material is (44,00 ± 0,56) % CV_r = 7 % by gravimetry.

The criteria for accepting results in a batch of analyses is:

Warning limits σ = 43,44 % to 44,56 % (m/m).

Action limits 2σ = 42,88 % to 45,12 % (m/m).

The repeatability (*r*) data on 6 analyses of an article gave a mean value of (23,17 ± 0,15) % CV_r = 7 % for similar articles.

Total plasticiser content by GC-MS:

The detection levels for GC-MS analysis for the phthalate esters are shown in Table A.2:

Table A.2 — Detection levels for GC-MS analysis for phthalate esters

Phthalate ester	DIDP	DINP	DBP	BBP	DNOP	DEHP
Detection level µg/ml	≤ 3,0	≤ 2,5	≤ 0,05	≤ 0,05	≤ 0,05	≤ 0,05

The detection limit for total plasticiser content by GC-MS ranges from 0,015 % to 0,00025 % (m/m) depending on phthalate being determined.

The repeatability (*r*) data on 6 analyses of a PVC reference material is (38,62 ± 0,83) % relative CV_r = ± 2 %.

The repeatability (*r*) data on 6 analyses of an article gave a mean value of (20,5 ± 0,71) % relative CV_r = ± 3 % for similar articles.

NOTE Coefficient variation *CV* is the ratio of the standard deviation to the average [12].

Annex B
(informative)

Suitable HPLC apparatus and method for the determination of 2,2-bis(4-hydroxyphenyl)propane [Bisphenol A] (BPA)

The following columns and operating conditions have been found to be suitable for the determination of BPA:

Column:	LATEK 250 x 4 Nucleosil 100-5-C18.
Column temperature:	25 °C.
Mobile phase:	Methanol : water (65 : 35); isocratic.
Flow:	0,6 ml/min.
Injection volume:	40 µl.
Detection:	BPA: FLD; excitation wavelength Ex = 275 nm, emission wavelength Em = 313 nm.
Retention time:	BPA; approximately 10,2 min.

Or

Column:	stainless steel 250 x 4.6 mm packed with C18-coated spherical silicagel, particle size 5 µm (load of 9% carbon and end-capped) (Hypersil ODS 5 µm).
Column temperature:	25 °C.
Mobile phase:	Methanol : water (70 : 30).
Flow:	1,0 ml/min.
Injection volume:	40 µl.
Detection:	BPA: FLD; excitation wavelength Ex = 275 nm, emission wavelength Em = 313 nm.
Retention time:	BPA; approximately 4,5 min.

Depending on the type of equipment used, the appropriate operating conditions may need to be established.

A typical chromatogram for BPA is shown in Figure B.1.

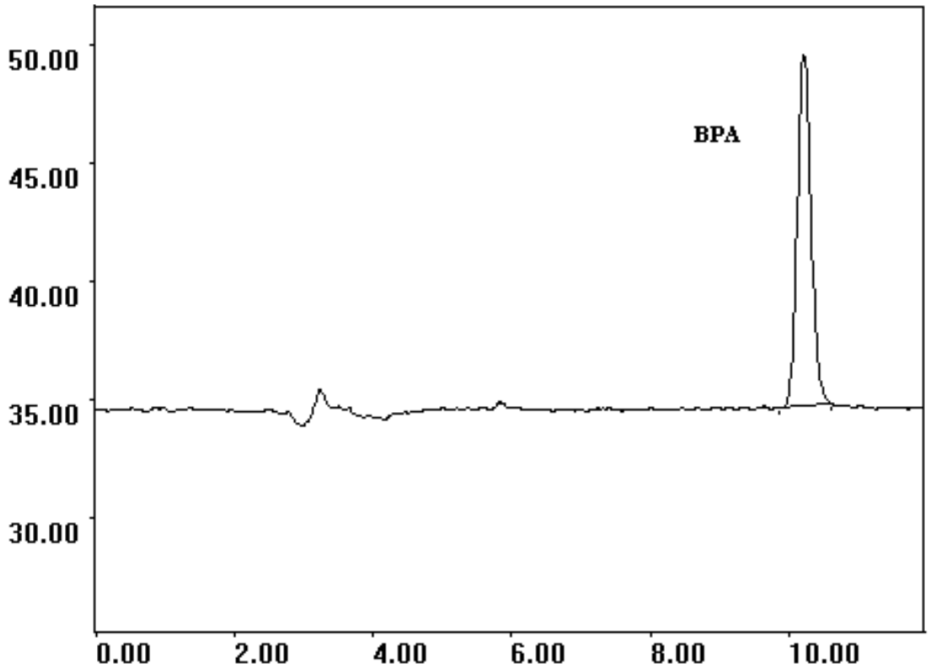


Figure B.1 – Chromatogram of BPA (absorbance (volt) v. retention time (min))

Precision data

This method has not been validated by collaborative trial. It has however been subject to a peer review procedure following method development work.

The within-laboratory relative standard deviation (RSD) of the method was found to be less than 4,5 % and typically less than 2,0 %.

Bibliography

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

[1] Commission Directive 2002/72/EC	Commission Directive of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs.
[2] Council Directive 89/109/EEC	Council Directive of 21 December 1989 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs.
[3] Commission Directive 82/711/EEC, and amendments 93/8/EEC and 97/48/EC	Commission Directive of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs.
[4] Council Directive 85/572/EEC	Council Directive of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs.
[5] European Parliament and Council Directive 94/27/EC	European Parliament and Council Directive of 30 June 1994 amending for the 12th time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.
[6] Council Directive 84/500/EEC	Council Directive of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs.
[7] Commission Decision 99/815/EC and subsequent extensions	Commission Decision of 7 December 1999 adopting measures prohibiting the placing on the market of toys and childcare articles intended to be placed in the mouth by children under three years of age made of soft PVC containing one or more of the substances di-iso-nonyl phthalate (DINP), di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), di-iso-decyl phthalate (DIDP), di-n-octyl phthalate (DNOP) and butylbenzyl phthalate (BBP).

Other publications

[8] EN ISO 9001, *Quality management systems – Requirements (ISO 9001:2000).*

[9] EN ISO 1302, *Geometrical Product Specifications (GPS) - Indication of surface texture in technical product documentation (ISO 1302:2002).*

[10] J. Haslam, H.A. Willis and D.C.M Squirrel, Identification and Analysis of Plastics: John Wiley & Son, 1981.

[11] prCEN/TS 13130-13:2003, *Materials and articles in contact with foodstuffs - Plastics substances subject to limitation - Part 13: Determination of 2,2-bis(4-hydroxyphenyl) propane (Bisphenol A) in food simulants.*

[12] ISO 3534-1:1993, *Statistics - Vocabulary and symbols - Part 1: Probability and general statistical terms.*

EN 14350-1 , *Child use and care articles - Drinking equipment - Part 1: General and mechanical requirements and tests.*

EN 14350-2 , *Child use and care articles - Drinking equipment - Part 2: Chemical requirements and tests.*