DRAFT FOR DEVELOPMENT

DD CEN/TS
13130-13:2005

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

ICS 67.250

BSI
British Standards

National foreword

This Draft for Development is the official English language version of CEN/TS 13130-10:2005.

This publication is not to be regarded as a British Standard.

It is being issued in the Draft for Development series of publications and is of a provisional nature because the method was not evaluated using recognized ring trial procedures. As a consequence there are no reproducibility data for the method. It should be applied on this provisional basis, so that information and experience of its practical application may be obtained.

Comments arising from the use of this Draft for Development are requested so that UK experience can be reported to the European organization responsible for its conversion to a European standard. A review of this publication will be initiated 2 years after its publication by the European organization so that a decision can be taken on its status at the end of its 3-year life. Notification of the start of the review period will be made in an announcement in the appropriate issue of *Update Standards*.

According to the replies received by the end of the review period, the responsible BSI Committee will decide whether to support the conversion into a European Standard, to extend the life of the Technical Specification or to withdraw it. Comments should be sent in writing to the Secretary of BSI Subcommittee CW/47/1 Migration from plastics, at British Standards House, 389 Chiswick High Road, London W4 4AL, giving the document reference and clause number and proposing, where possible, an appropriate revision of the text.

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

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the *BSI Catalogue* under the section entitled "International Standards Correspondence Index", or by using the "Search" facility of the *BSI Electronic Catalogue* or of British Standards Online.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Summary of pages

This document comprises a front cover, an inside front cover, the CEN/TS title page, pages 2 to 13 and a back cover.

The BSI copyright notice displayed in this document indicates when the document was last issued.

Amendments issued since publication

Amd. No.	Date	Comments

This Draft for Development was published under the authority of the Standards Policy and Strategy Committee on 16 September 2005

ISBN 0 580 46075 4

TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

CEN/TS 13130-13

February 2005

ICS 67.250

English version

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

Matériaux et objets en contact avec les denrées alimentaires - Substances dans les matières plastiques soumises à des limitations - Partie 13 : Détermination du 2,2-bis(4-hydroxyphènyl) propane (Bisphénol A) dans les simulants d'aliments

Werkstoffe und Gegenstände in Kontakt mit Lebensmitteln - Substanzen in Kunststoffen, die Beschränkungen unterliegen - Teil 13: Bestimmung von 2,2-Bis(4-Hydroxyphenyl)Propan (Bisphenol A) in Prüflebensmitteln

This Technical Specification (CEN/TS) was approved by CEN on 16 December 2004 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

CEN members are the national standards bodies of 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.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. CEN/TS 13130-13:2005: E

Contents

Foreword

This document (CEN/TS 13130-13:2005) has been prepared by Technical Committee CEN/TC 194 “Utensils in contact with food”, the secretariat of which is held by BSI.

This part of EN 13130 has been prepared within the Standards, Measurement and Testing project, MAT1-CT92-0006, “*Development of Methods of Analysis for Monomers*” and has been prepared by Subcommittee (SC 1) of TC 194 "Utensils in contact with food" as one of a series of test methods for plastics materials and articles in contact with foodstuffs.

This standard is intended to support Directives 2002/72/EC [1], 89/109/EEC [2], 82/711/EEC [3] and its amendments 93/8/EEC [4] and 97/48/EC [5], and 85/572/EEC [6].

At the time of preparation and publication of this part of EN 13130 the European Union legislation relating to plastics materials and articles intended to come into contact with foodstuffs is incomplete. Further Directives and amendments to existing Directives are expected which could change the legislative requirements which this standard supports. It is therefore strongly recommended that users of this standard refer to the latest relevant published Directive(s) before commencement of a test or tests described in this standard.

This part of EN 13130 should be read in conjunction with EN 13130-1.

Further parts of EN 13130, under the general title *Materials and articles in contact with foodstuffs - Plastics substances subject to limitation*, have been prepared, and others are in preparation, concerned with the determination of specific migration from plastics materials into foodstuffs and food simulants and the determination of specific monomers and additives in plastics. The parts of EN 13130 are as follows.

Part 1: *Guide to test methods for the specific migration of substances from plastics to foods and food simulants and the determination of substances in plastics and the selection of conditions of exposure to food simulants*

Part 2: *Determination of terephthalic acid in food simulants*

Part 3: *Determination of acrylonitrile in food and food simulants*

Part 4: *Determination of 1,3-butadiene in plastics*

Part 5: *Determination of vinylidene chloride in food simulants*

Part 6: *Determination of vinylidene chloride in plastics*

Part 7: *Determination of monoethylene glycol and diethylene glycol in food simulants*

Part 8: *Determination of isocyanates in plastics*

Part 9: *Determination of acetic acid, vinyl ester in food simulants*

Part 10: *Determination of acrylamide in food simulants*

Part 11: *Determination of 11-aminoundecanoic acid in food simulants*

Part 12: *Determination of 1,3-benzenedimethanamine in food simulants*

Part 13: *Determination of 2,2-bis(4-hydroxyphenyl)propane (Bisphenol A) in food simulants*

Part 14: *Determination of 3,3-bis(3-methyl-4-hydroxyphenyl)-2-indoline in food simulants*

Part 15: *Determination of 1,3-butadiene in food simulants*

Part 16: *Determination of caprolactam and caprolactam salt in food simulants*

Part 17: *Determination of carbonyl chloride in plastics*

Part 18: *Determination of 1,2-dihydroxybenzene, 1,3-dihydroxybenzene, 1,4-dihydroxybenzene, 4,4'-dihydroxybenzophenone and 4,4'dihydroxybiphenyl in food simulants*

Part 19: *Determination of dimethylaminoethanol in food simulants*

Part 20: *Determination of epichlorohydrin in plastics*

Part 21: *Determination of ethylenediamine and hexamethylenediamine in food simulants*

Part 22: *Determination of ethylene oxide and propylene oxide in plastics*

Part 23: *Determination of formaldehyde and hexamethylenetetramine in food simulants*

Part 24: *Determination of maleic acid and maleic anhydride in food simulants*

Part 25: *Determination of 4-methyl-pentene in food simulants*

Part 26: *Determination of 1-octene and tetrahydrofuran in food simulants*

Part 27: *Determination of 2,4,6-triamino-1,3,5-triazine in food simulants*

Part 28: *Determination of 1,1,1-trimethylolpropane in food simulants*

Parts 1 to 8 are European Standards. Parts 9 to 28 are Technical Specifications.

WARNING All chemicals are hazardous to health to a greater or lesser extent. It is beyond the scope of this Technical Specification to give instructions for the safe handling of all chemicals, that meet, in full, the legal obligations in all countries in which this Technical Specification may be followed. Therefore, specific warnings are not given and users of this Technical Specification should ensure that they meet all the necessary safety requirements in their own country.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this CEN Technical Specification: 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

2,2-bis(4-hydroxyphenyl)propane, hereinafter referred to as Bisphenol A, $C_{15}H_{16}O_2$, PM/Ref. 13480, is a monomer used in the manufacture of certain plastics materials and articles intended to come into contact with foodstuffs. After manufacture residual Bisphenol A can remain in the finished product and may migrate into foodstuffs coming into contact with that product.

The method has been pre-validated by a collaborative trial with three laboratories.

1 Scope

This document, part of EN 13130, specifies a method for the determination of Bisphenol A in the food simulants water, 3 % w/v acetic acid aqueous, 15 % v/v ethanol aqueous solution and rectified olive oil. The level of Bisphenol A monomer determined is expressed as milligrams Bisphenol A per kilogram of food simulant. The method is applicable to the quantitative determination of Bisphenol A at a minimum level of 0,2 mg/kg to 0,7 mg per kilogram of food simulants.

NOTE The method should also be applicable to other aqueous food simulants as well as to the other fatty food simulants, sunflower oil and a mixture of synthetic triglycerides.

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 13130-1:2004, *Materials and articles in contact with foodstuffs – Plastics substances subject to limitation – Part 1: Guide to test methods for the specific migration of substances from plastics to foods and food simulants and the determination of substances in plastics and the selection of conditions of exposure to food simulants.*

3 Principle

The level of Bisphenol A in aqueous food simulants is determined by high performance liquid chromatography (HPLC) with ultra violet (UV) detection. Olive oil test samples are extracted with a mixture of water/methanol and the resultant solution analyzed by HPLC. Calibration is achieved by analysis of relevant simulants containing known amounts of Bisphenol A. Confirmation of Bisphenol A is carried out by diode array detection.

4 Reagents

NOTE All reagents should be of recognized analytical quality unless otherwise stated.

4.1 Analyte

2,2-bis(4-hydroxyphenyl)propane (Bisphenol A or 4,4'-(methylethylidene)-bisphenol or 4,4'-isopropylidenediphenol), $C_{15}H_{16}O_2$, molecular weight: 228,28, purity > 99 %.

4.2 Chemicals

4.2.1 n-Hexane

4.2.2 Methanol

4.2.3 Water, deionized

4.3 Solutions

4.3.1 Extraction solvent, methanol/water = 1:1

Measure 100 ml of methanol (4.2.2) and 100 ml of water (4.2.3) and mix.

4.3.2 Mobile phase for HPLC, methanol/water = 70:30

Measure 500 ml of methanol (4.2.2) and 215 ml of water (4.2.3) and mix.

4.3.3 Stock solution of Bisphenol A in methanol at a defined concentration of approximately 0,38 mg/ml

Weigh to the nearest 0,1 mg approximately 37,5 mg of Bisphenol A (4.1.1) into a 100 ml volumetric flask. Dissolve the Bisphenol A in methanol and make up to the mark with methanol (4.2.2).

Calculate the concentration in micrograms of Bisphenol A per millilitre of solution.

Repeat the procedure to obtain a second stock solution.

NOTE The solution can be stored in a well closed container in dark for a maximum of 3 months at any temperature between +20 °C and –20 °C.

5 Apparatus

NOTE An instrument or item of apparatus is listed only where it is special or made to a particular specification, usual laboratory glassware and equipment being assumed to be available.

5.1 High performance liquid chromatograph, preferably, equipped with an automatic 20 µl loop injector and a variable wavelength UV detector connected to an integrator.

5.2 HPLC column, capable of separating Bisphenol A fully from peaks originating from the simulants and/or solvents used.

Appropriate operating conditions shall be established for the specific equipment used for the determination.

NOTE The following column has been found to be suitable:

column: stainless steel 250 x 4,6 mm packed with C18 coated spherical silica gel, particle size 5 µm, (load of 9 % carbon and end-capped);

mobile phase: methanol/water 70 : 30 (4.3.2);

flow rate: 1 ml/min;

detection: UV 280 nm.

5.3 Mechanical shaker (Vortex)

5.4 Micro syringes, 10 µl, 50 µl and 1 000 µl.

5.5 Test tubes, volume 10 ml, size 10 cm x 1,5 cm.

6 Samples

6.1 Test sample preparation

6.1.1 General

Laboratory samples of the food simulants to be analyzed shall be obtained as described in EN 13130-1. Samples shall be kept refrigerated at + 4 °C in closed containers with the exclusion of light. Analyte-free samples of relevant food simulants of the same type as those to be analyzed shall also be prepared for calibration purposes.

6.1.2 Aqueous solutions

Transfer approximately 1 ml of the food simulants obtained from the migration experiment (see EN 13130-1) into a vial suitable for HPLC injections.

6.1.3 Olive oil

Weigh 1 g ± 0,01 g of olive oil, obtained from the migration experiment (see EN 13130-1), into a test tube (5.5). Add by volumetric pipette 3,0 ml of n-hexane (4.2.1), mix well and add by volumetric pipette 2,0 ml methanol/water (4.3.1). Mix for 1 min with a mechanical shaker (5.3). Allow the phases to separate for 30 min. Retract by means of a pipette a part of the, lower, aqueous layer and transfer the solution into a vial suitable for HPLC injections.

6.2 Blank sample preparation

Treat food simulants which have not been in contact with packaging material in the same way as described in 6.1.

6.3 Calibration sample preparation

6.3.1 Aqueous food simulant calibration samples

Transfer with a micro syringe (5.4) into a series of six 25 ml volumetric flasks 0 µl, 20 µl, 100 µl, 200 µl, 300 µl and 400 µl of the standard stock solution (4.3.3) and make up to the mark with the appropriate analyte-free food simulant, water, 3 % w/v aqueous acetic acid or 15 % v/v aqueous ethanol, and mix thoroughly. The calibration solutions thus obtained contain 0 µg/ml and approximately 0,30 µg/ml, 1,5 µg/ml, 3,0 µg/ml, 4,5 µg/ml or 6,0 µg of Bisphenol A per millilitre of food simulant.

Calculate the exact concentrations of Bisphenol A in the calibration samples in micrograms per millilitre corresponding directly to milligrams per kilogram.

NOTE Commission Directive 90/128/EEC [1] states that the specific gravity of all simulants should conventionally be assumed to be '1'. Milligrams of substance released per litre of simulant will thus correspond numerically to milligrams of substance released per kilogram of simulant and, taking into account of the provisions laid down in Directive 82/711//EEC [3], to milligrams of substance released per kilogram of foodstuff.

For at least one food simulant, repeat the procedure using the second stock solution (4.3.3).

6.3.2 Olive oil calibration samples

Weigh 1 g ± 0,01 g of olive oil into a series of six test tubes. Transfer with a micro syringe (5.4) 0 µl, 1 µl, 4 µl, 8 µl, 12 µl and 16 µl of the standard stock solution (4.3.3) into the test tubes. The calibration samples thus obtained contain 0 µg and approximately 0,30 µg/gm, 1,5 µg/gm 3,0 µg/gm, 4,5 µg/gm and 6,0 µg of Bisphenol A per gram of olive oil.

Add by volumetric pipette 3,0 ml of n-hexane (4.2.1), mix and add by volumetric pipette 2,0 ml of methanol/water = 1:1 (4.3.2). Shake for 1 min using a mechanical shaker (5.3). Allow the phases to separate. Retract by means of a pipette a part of the, lower, aqueous) layer and transfer this solution into a vial suitable for HPLC injections.

Calculate the exact concentrations of Bisphenol A in the calibration samples in micrograms per gram olive corresponding directly to milligrams per kilogram.

Repeat the procedure using the second stock solution (4.3.3).

7 Procedure

7.1 HPLC analysis

When starting measurements, examine the baseline stability and response linearity of the detector.

The detector shall be able to detect at least 6 ng on column of Bisphenol A at a signal to noise ratio of 3:1.

The same operating conditions of the HPLC system shall be maintained throughout the measurements of all sample and calibration solutions. Each test solution shall be injected, at least, in duplicate.

NOTE Under the conditions given in 5.2 the retention time for Bisphenol A was determined to be 4,5 min.

7.2 Calibration

Analyze each of the calibration solutions as prepared in 6.3.1 and 6.3.2 applying duplicate injections. Measure the peak height or area of Bisphenol A at 280 nm. Construct a calibration curve plotting these values against the concentration of Bisphenol A in milligrams per kilogram in the calibration solutions.

The calibration curves shall be rectilinear with a correlation coefficient of 0,996 or better.

The two sets of calibrant solutions made from independently prepared stock solutions shall be cross-checked by generating two calibration curves which, on the basis of peak ratio measurement, shall agree to within ± 5 % of one another.

7.3 Execution of determination

Analyze the test sample solutions, prepared as described in 6.1 and 6.2, applying the HPLC conditions used for the calibration solutions. Inject each of the test sample solutions in duplicate. Measure the peak height or area of Bisphenol A and either read the Bisphenol A concentration, in milligrams per kilogram, from the calibration curve or calculate it from the regression coefficient.

7.4 HPLC interferences

Following the method described, no interferences have been detected in the aqueous food simulants. In the extracts obtained from the olive oil, some interference was detected at the level of 0,3 mg/kg. Other batches of oil may have different levels of interfering components.

If the analysis of the zero point calibration sample (6.3) shows a peak in the Bisphenol A region corresponding to less than 0,3 mg/kg when calculated according to 8.1.1 and the absolute area of duplicates does not vary by more than 10 %, the peak height or area of the zero point calibration sample shall be subtracted from those of the test sample and the calibration samples and the data plotted as in 7.2. If the interference corresponds to more than 0,3 mg/kg, the method of standard addition shall be used.

8 Expression of results

8.1 Calculation of analyte level

NOTE The following calculations assume that for all measurements exactly the same mass or volume of water, 3 % w/v aqueous acetic acid, 15 % v/v aqueous ethanol and olive oil has been used.

8.1.1 Graphical determination

Calculate the average of peak area/height values obtained from the test samples in accordance with 7.3 and read the Bisphenol A concentration of the test samples from the calibration graph (7.2).

8.1.2 Calculation from the regression parameters

If the regression line equation is:

$$y = (a \times x) + b$$

where

y is the peak area of Bisphenol A;

a is the slope of the regression line in milligrams per kilogram;

x is the concentration of Bisphenol A in the food simulant in milligrams per kilogram;

b is the intercept of the regression line,

the concentration of Bisphenol A concentration in the food simulant is given by:

$$C_{BISfs} = \frac{y - b}{a}$$

where

C_{BISfs} is the concentration of Bisphenol A in milligrams per kilogram.

Both procedures yield directly the Bisphenol A concentration in the food simulant in milligrams per kilogram.

The method applying calculation from the regression parameters is the preferred method.

8.1.3 Calculation of the specific Bisphenol A migration

Depending on the fill volume of the test material and on the surface area/food simulant ratio, the Bisphenol A concentration in the test sample, as determined according to 8.1.1 or 8.1.2, may need mathematical transformation to calculate the specific migration value to be compared with the specific migration limit (SML). For guidance see EN 13130-1:2004, Clause 13.

8.2 Precision

8.2.1 Validation

This method was pre-evaluated in 1994/95 by a collaborative trial with three laboratories; in each laboratory a within-laboratory precision experiment using the four official EU food simulants for establishment of precision data at the restriction criterion was carried out as well as migration testing using a polycarbonate 6 sample being in contact for 10 d at 40 °C with 15 % v/v aqueous ethanol and olive oil, respectively.

8.2.2 Repeatability

Evaluation of the three within-laboratory precision experiment results, according to ISO 5725, at a concentration of 4 mg Bisphenol A/kg food simulant, yielded the following performance characteristics (lab 1/lab 2/lab 3) at the 95 % probability level:

Repeatability: r = 0,06/0,05/0,40 mg Bisphenol A per kilogram of water;

r = 0,11/0,10/0,30 mg Bisphenol A per kilogram of 3 % w/v aqueous acetic acid;

r = 0,14/0,14/0,10 mg Bisphenol A per kilogram of 15 % v/v aqueous ethanol;

r = 0,11/0,38/1,1 mg Bisphenol A per kilogram olive oil.

8.2.3 Detection limit

The within-laboratory detection limits (WDL), based on the calibration curve method according to DIN 32645, were found to be in the range of 0,05 mg/kg to 0,7 mg per kilogram of food simulant. Thus the method is capable of quantitative determination of Bisphenol A at a minimum level of 0,7 mg per kilogram of food simulant.

9 Confirmation

9.1 Requirement for confirmation

If specific migration of Bisphenol A, calculated in accordance with the procedure given in EN 13130-1 from the analyte level calculated according to 8.1, exceeds the restriction criterion, e.g. SML = 3 mg/kg, the result of the determination shall be confirmed by the method described in 9.2.

The confirmation is qualitative in the sense that it should demonstrate the correct identity of the measured analyte and the absence of interferences. For the purpose of quantification the result as calculated according to 8.1.3 shall be taken as the true value.

9.2 Confirmation by HPLC analysis using diode array detection

Re-analyze the test samples, blank and calibration samples prepared in 6.1 to 6.3 using the same HPLC system in combination with diode array detection. Bisphenol A can be identified as having an absorbance peak maximum at 230 and 283 nm. The test sample has to provide the same UV spectrum as obtained from the calibration samples. A measured ratio of the absorbance at 220 nm:230 nm:283 nm was found to be 100:108:25. To check for peak purity, record the spectral profiles over the range of 200 nm to 350 nm at the front, apex and tail of the peak with the retention of Bisphenol A. If the peak is pure, the overlaid spectral profiles of the front, apex, and tail of the peak should be identical. If the three profiles are normalized they superimpose on top of each other.

NOTE Slight interference has been observed at the front of the Bisphenol A peak when an extract of olive oil was analyzed. This interference may give reason to deviations in the spectrum of the Bisphenol A.

10 Test report

The test report shall include the following, where applicable:

a) all information necessary for complete identification of the sample, e.g. chemical type, trade mark, grade, batch number, thickness, etc.;

b) form of the plastics, e.g. film, bottle, pot, etc.;

c) use/class of food for which the sample is intended to contact, where known, and where possible food classification reference number; see Table 2 of EN 13130-1:2004;

d) intended conditions of use, where known e.g. time/temperature;

e) conditions of the test;

   1) part(s) of EN 13130 used;

   2) foodstuffs or food simulants used;

   3) duration and temperature, and relation with "Conditions of contact in worst foreseeable use", as given in Table 3 of EN 13130-1:2004;

   4) area and geometry of the test specimen;

   5) volume of foodstuff or food simulant used where appropriate;

f) any departures from the standard method, reasons for the departures;

g) any particular requirements of the parts of this document;

h) any relevant comments on the test results;

i) details of any confirmation procedure(s);

j) individual triplicate or quadruplicate test results, and the mean of these results expressed in milligrams of 2,2-bis(4-hydroxyphenyl)propane (Bisphenol A) per kilogram of food simulant.

Bibliography

[1] Commission of the European Communities, Commission Directive of 23 February 1990 relating to plastics materials and articles intended to come into contact with foodstuffs (90/128/EEC), Official Journal of the European Communities, 13 December 1990, no. L349, p26. Corrigendum of the previous publication, Official Journal of the European Communities, 21 March 1990, no. 75. p19.

[2] Commission of the European Communities, Council Directive of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuff (89/109/EEC), Official Journal of the European Communities, 11 February 1989, no. L 40, p 38.

[3] Commission of the European Communities, Council Directive of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs (82/711/EEC), Official Journal of the European Communities, 23 October 1982, no. L 297, p 26.

[4] Commission of the European Communities, Commission Directive of 15 March 1993 amending Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs (93/8/EEC), Official Journal of the European Communities, 14 April 1993, no. L 90, p 22.

[5] Commission of the European Communities, Commission Directive of 97/48/EC of 29 July 1997 amending Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs, Official Journal of the European Communities, 12 August 1997, no. L 222, p 10.

[6] Commission of the European Communities, Council Directive of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastics materials and articles intended to come into contact with foodstuffs (85/572/EEC), Official Journal of the European Communities, 31 December 1985, no. L372, p14.

[7] ISO 5725, *Accuracy (trueness and precision) of measurement methods and result.*

[8] DIN 32645, *Chemical analysis; decision limit; detection limit and determination limit; estimation in case of repeatability; terms, methods, evaluation.*

BSI — British Standards Institution

BSI is the independent national body responsible for preparing British Standards. It presents the UK view on standards in Europe and at the international level. It is incorporated by Royal Charter.

Revisions

British Standards are updated by amendment or revision. Users of British Standards should make sure that they possess the latest amendments or editions.

It is the constant aim of BSI to improve the quality of our products and services. We would be grateful if anyone finding an inaccuracy or ambiguity while using this British Standard would inform the Secretary of the technical committee responsible, the identity of which can be found on the inside front cover. Tel: +44 (0)20 8996 9000. Fax: +44 (0)20 8996 7400.

BSI offers members an individual updating service called PLUS which ensures that subscribers automatically receive the latest editions of standards.

Buying standards

Orders for all BSI, international and foreign standards publications should be addressed to Customer Services. Tel: +44 (0)20 8996 9001. Fax: +44 (0)20 8996 7001. Email: orders@bsi-global.com. Standards are also available from the BSI website at http://www.bsi-global.com.

In response to orders for international standards, it is BSI policy to supply the BSI implementation of those that have been published as British Standards, unless otherwise requested.

Information on standards

BSI provides a wide range of information on national, European and international standards through its Library and its Technical Help to Exporters Service. Various BSI electronic information services are also available which give details on all its products and services. Contact the Information Centre. Tel: +44 (0)20 8996 7111. Fax: +44 (0)20 8996 7048. Email: info@bsi-global.com.

Subscribing members of BSI are kept up to date with standards developments and receive substantial discounts on the purchase price of standards. For details of these and other benefits contact Membership Administration. Tel: +44 (0)20 8996 7002. Fax: +44 (0)20 8996 7001. Email: membership@bsi-global.com.

Information regarding online access to British Standards via British Standards Online can be found at http://www.bsi-global.com/bsonline.

Further information about BSI is available on the BSI website at http://www.bsi-global.com.

Copyright

BSI
389 Chiswick High Road
London
W4 4AL