SLOVENSKI STANDARD
oSIST prEN IEC 62321-13:2025

01-april-2025

Določevanje posameznih snovi v elektrotehničnih izdelkih - 13. del: Določevanje bisfenola A v plastiki s tekočinsko kromatografijo - določevanje s serijo diod (LC-DAD), tekočinsko kromatografijo - masno spektrometrijo (LC-MS) in tekočinsko kromatografijo - tandemsko masno spektrometrijo (LC-MS/MS)

Determination of certain substances in electrotechnical products - Part 13: Bisphenol A in plastics by liquid chromatography-diode array detection (LC-DAD), liquid chromatography-mass spectrometry (LC-MS) and liquid chromatography-tandem mass spectrometry (LC-MS/MS)

Détermination de certaines substances dans les produits électrotechniques - Partie 13: Bisphénol A dans les plastiques par chromatographie en phase liquide avec détection à barrettes de diodes (LC-DAD), par chromatographie en phase liquide avec spectrométrie de masse (LC-MS) et par chromatographie en phase liquide avec spectrométrie de masse en tandem (LC-MS/MS)

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ASPECTS CONCERNED: Environment	
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TITLE:

Determination of certain substances in electrotechnical products – Part 13: Bisphenol A in plastics by liquid chromatography-diode array detection (LC-DAD), liquid chromatography-mass spectrometry (LC-MS) and liquid chromatography-tandem mass spectrometry (LC-MS/MS)

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CONTENTS

FOREWORD 3
INTRODUCTION 5
1 Scope 6
2 Normative references 6
3 Definitions 6
3.1 Terms and definitions 6
3.2 Abbreviations 6
4 Principle 7
5 Reagents and materials 7
6 Apparatus 8
7 Sampling 8
8 Procedure 8
8.1 General instructions for the analysis 8
8.2 Sample preparation 9
8.2.1 Stock solution 9
8.2.2 Extraction 9
8.3 Instrumental parameters 9
8.3.1 Stationary phase 9
8.3.2 Liquid (mobile) phase 9
8.4 Calibrants 9
8.5 Calibration 10
8.5.1 General 10
8.5.2 Standard solutions 10
9 Calculation of BPA concentration 11
9.1 General 11
9.2 Calculation 11
10 Precision data 12
10.1 LC-DAD Method 12
10.2 LC-MS Method 13
10.3 LC-MS/MS Method 15
11 Quality assurance and quality control 16
11.1 Performance 16
11.2 Internal control samples and blanks 17
11.3 Method detection limit and reporting limit 17
12 Test report 18
Annex A (informative) Conditions of each instrument 19
Annex B (informative) Examples of chromatograms at suggested conditions 22
Annex C (informative) Results of preliminary international Interlaboratory study (Pre-IIS 13) 24
Annex D (informative) Results of International Interlaboratory study (IIS 13) 27

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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DETERMINATION OF CERTAIN SUBSTANCES IN ELECTROTECHNICAL PRODUCTS –

Part 13: Bisphenol A in plastics by liquid chromatography-diode array detector (LC-DAD), liquid chromatography-mass spectrometry (LC-MS) and liquid chromatography-tandem mass spectrometry (LC/MS-MS)

FOREWORD

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The text of this International Standard is based on the following documents:

FDIS	Report on voting
XX/XX/FDIS	XX/XX/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

The widespread use of electrotechnical products has drawn increased attention to their impact on the environment. In many countries this has resulted in the adaptation of regulations affecting waste, substances and energy use of electrotechnical products.

The use of certain substances (e.g. lead (Pb), cadmium (Cd), mercury (Hg) and polybrominated diphenyl ethers (PBDEs)), phthalates in electronical products is a source of concern in current and proposed regional legislation.

The purpose of the IEC 62321 series is therefore to provide test methods that will allow the electrotechnical industry to determine the levels of certain substances of concern in electrotechnical products on a consistent global basis.

This first edition of IEC 62321-13 introduces a new subject covering Bisphenol A in the IEC 62321 series.

WARNING — Persons using this International Standard should be familiar with normal laboratory practice. This standard does not purport to address all of the safety problems, if any, associated with its use. It is the responsibility of the user to establish appropriate safety and health practices and to ensure compliance with any national regulatory conditions.

DETERMINATION OF CERTAIN SUBSTANCES IN ELECTROTECHNICAL PRODUCTS –

Part 13: Bisphenol A in plastics by liquid chromatography-diode array detector (LC-DAD), liquid chromatography-mass spectrometry (LC-MS) and liquid chromatography-tandem mass spectrometry (LC/MS-MS)

1 Scope

This International standard specifies three techniques for the determination of free Bisphenol A (BPA) in plastics of electrotechnical products.

The liquid chromatography – diode array detector (LC-DAD) and liquid chromatography mass spectrometry (LC-MS) and liquid chromatography tandem mass spectrometry (LC-MS/MS). These test methods are described in the normative part of this standard. These test methods have been evaluated for use with PC, PC/ABS, PP matrices containing free BPA between 20 mg/kg to 500 mg/kg as shown in the Pre-IIS 13 results in Annex C and IIS 13 results in Annex D. The use of these methods for BPA concentration ranges of plastics, other than those specified in Annex C, Annex D has not been evaluated.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

IEC 62321-1 – *Determination of certain substances in electrotechnical products – Part 1: Introduction and overview*

IEC 62321-2 – *Determination of certain substances in electrotechnical products – Part 2: Disassembly, disjunction and mechanical sample preparation*

ISO 3696:1987 – *Water for analytical laboratory use – Specification and test*

3 Definitions

3.1 Terms and definitions

For the purposes of this document, the terms and definitions provided in IEC 62321-1 and the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1.1 Free Bisphenol A

Refers to chemically unbound BPA, as present in material.

3.2 Abbreviations

For the purpose of this document, the following abbreviations apply.

ABS	Acrylonitrile-butadiene-styrene

API-ES	Atmospheric pressure ionization – Electrospray
BPA	Bisphenol A
BPC	Bisphenol C
CCC	Continuing calibration check standard
CRM	Certified reference material
IS	Internal standard
LC	Liquid chromatography
LC-DAD	Liquid chromatography-diode array detector
LC-MS	Liquid chromatography-mass spectrometry
LC-MS/MS	Liquid chromatography-tandem mass spectrometry
MDL	Method detection limit
PC	Polycarbonate
PC/ABS	Polycarbonate/ Acrylonitrile-butadiene-styrene
PP	Polypropylene
PTFE	Polytetrafluoroethylene
QC	Quality control
RSD	Relative standard deviation
TRM	Traceable reference material

4 Principle

Free BPA is determined using ultrasonic extraction followed by high performance liquid chromatography separation and tandem mass spectrometry and liquid chromatography-diode array detection. When analysing free BPA in PC and type of epoxy resin samples, thermal stress to the sample should be avoided during sample preparation (see section 7), as heat can affect the result.

5 Reagents and materials

The reagent chemicals used for the tests described in this standard shall have a minimum purity as described in a) to i). This is intended to ensure the reagents are free from contamination and prevent proliferation of blank values. There is a risk of elevated blank values due to the ubiquitous nature of BPA (CAS #80-05-7). Laboratories should assure to verify the blank value of the test method especially in case the calibration curve shows an offset.

a) Methanol (Purity LC grade or higher);

b) Tetrahydrofuran (Purity LC grade or higher);

c) Water (Purified water, quality of the mobile phase ingredients and solution or according to ISO 3696:1987, Grade 1);

d) Acetonitrile (Purity LC grade or higher);

e) Mixed solvent solution (1:1 Methanol and water),

- Add 500 ml methanol and 500 ml water to 1 l beaker and mix.

f) 10 mM ammonium acetate buffer solution

- Add 0,771 g ammonium acetate in a 1 l beaker (6.h), dissolve with a little purified water (5.c), then add 900 ml purified water. Transfer to 1 l volumetric flask and add 10 ml acetonitrile and dilute with purified water to the marked line.

g) Calibrants, BPA (Purity of greater than a mass fraction of 99 %);

h) Internal standard used to correct for injection (e.g. BPA-d_{16}, BPA-d_8, BPC);

i) 0,04 % Phosphoric acid buffer solution

- Add about 0,471 ml 85 % Phosphoric acid in a 1 l volumetric flask (6.b) and dilute with purified water to the marked line.

NOTE To prevent exothermal reaction fill volumetric flask to half of water and then add acid. Then fill to the mark with purified water.

6 Apparatus

The following items shall be used for the analysis:

a) Analytical balance having an accuracy of 0,000 1 g;

b) 10 ml, 100 ml, 1 l volumetric flasks (glass);

c) Ultrasonic bath; with a minimum power of 200 W and a bath area of 706 cm^2, corresponding to 0,28 W/cm^2, without a basket and with an internal or external thermostat.

d) Pasteur pipette (glass);

e) 1,5 ml sample vials with 100 µl glass insert and a screw cap with polytetrafluoroethylene (PTFE) gasket or, depending on the analytical system, a comparable sample receptacle;

f) 0,45 µm PTFE filter membrane;

g) Centrifuge; with over 3 000 r/min

h) 1 l beaker (glass)

i) Minimum 40 ml vial (glass)

7 Sampling

As described in IEC 62321-2 unless otherwise indicated, the following procedure shall be used.

Cut samples approximately to a size of 2 mm x 2 mm, and homogenise. Contact with possible sources of BPA-contamination shall be avoided during sampling.

NOTE Heat can cause the formation of additional free BPA. Avoid using devices that generate heat (e.g. circular saw).

8 Procedure

8.1 General instructions for the analysis

The following general instructions shall be followed:

a) In order to reduce blank values, ensure the cleanliness of all glass and analytical equipment;

b) If the amount of BPA in the sample is considerably above the calibration range, it will be necessary to carry out the analysis using an adjusted sample size or by repeating the analysis using an extract that has been appropriately diluted prior to internal standard addition.

8.2 Sample preparation

8.2.1 Stock solution

a) Standard solution for calibration: Prepare a standard solution containing Bisphenol A 1 000 µg/ml in Tetrahydrofuran (5.b).

b) Internal standard for LC-MS and LC-MS/MS: 4 µg/ml in Tetrahydrofuran (5.b) (e.g. BPC, BPA-d_{16}, BPA-d_8)

c) Internal standard for LC-DAD: 40 µg/ml in Tetrahydrofuran (5.b) (e.g. BPC)

d) Dilution solution: 10 ml of internal standard (8.2.1.b or 8.2.1.c) in 30 ml of mixed solvent (5.e)

8.2.2 Extraction

a) Weigh approximately 1 g of the sample and transfer it into a tared vial. Record the mass to the nearest 0,01 g. Lower sample weights can be tested.

b) Add 10 ml of IS solution (8.2.1.b or 8.2.1.c) to the vial;

c) Tightly cap the sample vial. Place it in an ultrasonic bath (6.c) and sonicate at 40 °C for 60 min.;

d) After the sample has extracted, allow the vial to cool to ambient temperature;

e) Accurately add 30 ml of mixed solvent (5.e) dropwise into the vial to precipitate the sample matrix;

f) Allow the resulting extracted solution to stand at room temperature for 30 min.;(When necessary use centrifuge (6.g) for 10 min to precipitated the sample matrix down with 3 000 r/min)

g) Filter the sample solution through a 0,45 µm PTFE membrane (6.f) and transfer into a vial for LC analysis.

8.3 Instrumental parameters

Different conditions might be necessary to optimize a specific LC system to achieve effective determination of free BPA and meet the QC and MDL requirements. The following parameters have been found suitable and are provided as an example:

NOTE Additional detailed instrument parameters are described in Annex A and Annex B

8.3.1 Stationary phase

a) C_{18} Column, 150 mm x 2,1 mm ID, 5 µm or equivalent;

b) C_{18} Column, 250 mm x 4,6 mm ID, 5 µm or equivalent.

8.3.2 Liquid (mobile) phase

Water (5.c) and Acetonitrile (5.d) are used as liquid phases.

8.4 Calibrants

Table 1 shows BPA reference materials suitable for this analysis.

Table 1 – Commercially available BPA reference material considered suitable for this analysis

Compound name	CAS Number
BPA	80-05-7
BPA-d_{16}	96210-87-6
BPA-d_8	92739-58-7