

**Materials and articles in contact with
foodstuffs - Certain epoxy derivatives
subject to limitation - Determination of
BADGE, BFDGE and their hydroxy and
chlorinated derivatives in food simulants**

Materials and articles in contact with foodstuffs -
Certain epoxy derivatives subject to limitation -
Determination of BADGE, BFDGE and their hydroxy
and chlorinated derivatives in food simulants

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 15136:2006 sisaldab Euroopa standardi EN 15136:2006 ingliskeelset teksti. Käesolev dokument on jõustatud 28.04.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 15136:2006 consists of the English text of the European standard EN 15136:2006. This document is endorsed on 28.04.2006 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.
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Käsitlusala: This European standard describes a method for the determination of BADGE, BFDGE and their reaction products in food simulants: distilled water, 3 % w/v aqueous acetic acid, 10 % v/v aqueous ethanol solution and olive oil or sunflower oil.	Scope: This European standard describes a method for the determination of BADGE, BFDGE and their reaction products in food simulants: distilled water, 3 % w/v aqueous acetic acid, 10 % v/v aqueous ethanol solution and olive oil or sunflower oil.
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Võtmesõnad:

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English Version

Materials and articles in contact with foodstuffs - Certain epoxy derivatives subject to limitation - Determination of BADGE, BFDGE and their hydroxy and chlorinated derivatives in food simulants

Matériaux et objets en contact avec les denrées alimentaires - Dérivés époxy soumis à des limitations - Détermination du BADGE, du BFDGE et de leurs dérivés hydroxylés et chlorés dans les simulants d'aliments

Werkstoffe und Gegenstände in Kontakt mit Lebensmitteln - Bestimmte Epoxyderivate, die Beschränkungen unterliegen - Bestimmung von BADGE, BFDGE und deren Hydroxy- und Chlorderivaten in Prüflebensmitteln

This European Standard was approved by CEN on 23 January 2006.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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Contents

Page

Foreword.....	3
Introduction	4
1 Scope.....	5
2 Normative references	5
3 Principle	5
4 Reagents	6
5 Apparatus.....	9
6 Samples.....	11
7 Procedure.....	13
8 Confirmation	17
9 Precision	17
10 Test report.....	18
Annex A (informative) Structures of the main compounds cited in this standard.....	20
Annex B (informative) Principle of the determination of BADGE, BFDGE and their hydroxyl and chlorinated derivatives in food simulants	24
Annex C (informative) Typical chromatograms of BADGE, BFDGE and some of their derivatives.....	25
Annex D (informative) Determination of BADGE and its hydrolysis and hydroxychlorinated products in foodstuffs.....	29
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directives	30
Bibliography	31

Foreword

This document (EN 15136:2006) has been prepared by Technical Committee CEN/TC 194 "Utensils in contact with food", the secretariat of which is held by BSI.

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 September 2006, and conflicting national standards shall be withdrawn at the latest by September 2006.

This document 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 document.

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

WARNING: All chemicals are hazardous to health to a greater or lesser extent. It is beyond the scope of this European standard to give instructions for the safe handling of all chemicals, that meet, in full, the legal obligations in all countries in which this European standard may be followed. Therefore, specific warnings are not given and users of this European standard 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 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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl)ether (BADGE) and bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ether (BFDGE) are monomers used in the manufacture of certain polymeric food contact materials and articles.

The main application of these monomers is in epoxy coatings for cans and ends. The substances may also be used in organosol coatings.

After the manufacture, residues of the substances or the reaction products can remain in the finished product and might migrate into foodstuffs coming into contact with that product.

The analytical method described allows for the determination of BADGE, BFDGE and their reaction products in aqueous and fatty food simulants.

1 Scope

This European standard describes a method for the determination of BADGE, BFDGE and their reaction products in food simulants: distilled water, 3 % w/v aqueous acetic acid, 10 % v/v aqueous ethanol solution and olive oil or sunflower oil.

A high performance liquid chromatography (HPLC) method is employed based on reversed phase HPLC and fluorescence detection.

The method is capable of determining BADGE and its derivatives at a minimum level of 0,05 µg/ml food simulant.

BFDGE and its derivatives can be determined at a minimum level of 0,1 µg/ml food simulant.

Direct HPLC analysis of the migration solutions may result in chromatograms difficult to interpret, due to interference from other components or the instability of the monomers resulting in a complex mixture of derivatives and/or reaction products. By forced hydrolysis of all epoxy groups and their reaction products, the quantification of the relevant substances is simplified and in addition the identities of the substances are indicatively confirmed.

NOTE In this European standard the term "BADGE, BFDGE and their derivatives" refers to the substances listed in Directive 2002/16/EC [1] and its amendment, Directive 2004/13/EC [2]. These substances are listed in 4.1.

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

ISO 648, *Laboratory glassware – One-mark pipettes*

3 Principle

3.1 Determination of BADGE, BFDGE and their derivatives in food simulants

Proper quantification of the sum of BADGE, BFDGE and/or their derivatives is obtained by analysing the simulants twice: a first analysis of the simulant as obtained from the migration is performed and, if necessary, the substances are fully hydrolysed and the hydrolysed substances are determined in a second HPLC analysis. This second analysis is used for confirmation and final quantification of the sum of BADGE or BFDGE and their derivatives as the bis(diols) derivatives.

In the first instance, after the migration period, samples from aqueous food simulants are directly injected into a reverse phase HPLC column and the substances are separated using a gradient elution profile. For fatty food simulants, the substances are extracted with acetonitrile followed by HPLC