Materials and articles in contact with foodstuffs - Plastics - Part 15 : Alternative test methods to migration into fatty food simulants by rapid extraction into iso-octane and/or 95% ethanol

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 1186-15:2002 sisaldab Euroopa standardi EN 1186-15:2002 ingliskeelset teksti. Käesolev dokument on jõustatud 18.10.2002 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 1186-15:2002 consists of the English text of the European standard EN 1186-15:2002. This document is endorsed on 18.10.2002 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This European Standard specifies two alternative test methods, in the sense of an extraction test with a more severe' test character, for the assessment of the overall migration into fatty food simulants.Method A is based on the determination of the extraction of migrateable substances from plastics which are intended to come into contact with foodstuffs, by total immersion in non-polar, iso-octane, and/or polar, ethanol, solvents depending on the polarity of the packaging material	**Scope:** This European Standard specifies two alternative test methods, in the sense of an extraction test with a more severe' test character, for the assessment of the overall migration into fatty food simulants.Method A is based on the determination of the extraction of migrateable substances from plastics which are intended to come into contact with foodstuffs, by total immersion in non-polar, iso-octane, and/or polar, ethanol, solvents depending on the polarity of the packaging material

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Materials and articles in contact with foodstuffs - Plastics - Part 15: Alternative test methods to migration into fatty food simulants by rapid extraction into iso-octane and/or 95 % ethanol

Matériaux et objets en contact avec les denrées alimentaires - Matière plastique - Partie 15: Méthodes d'essai alternatives pour la migration dans les simulants alimentaires gras par extraction rapide dans l'iso-octane et/ou l'éthanol à 95 %

Werkstoffe und Gegenstände in Kontakt mit Lebensmitteln - Kunststoffe - Teil 15: Alternative Prüfverfahren zur Migration in fettige Prüflebensmittel durch Schnellextraktion in Iso-Octan und/oder 95%iges Ethanol

This European Standard was approved by CEN on 29 April 2002.

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

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Foreword

This document EN 1186-15:2002 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 March 2003, and conflicting national standards shall be withdrawn at the latest by March 2003.

This European Standard has been prepared as one of a series of methods of test for plastics materials and articles in contact with foodstuffs.

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

At the time of preparation and publication of this standard 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 any of the test or tests described in this standard.

EN 1186-15 should be read in conjunction with EN 1186-1.

Further parts of this standard have been prepared concerned with the determination of overall migration from plastics materials into food simulants. Their titles are as follows:

EN 1186 Materials and articles in contact with foodstuffs – Plastics –

Part 1	Guide to the selection of conditions and test methods for overall migration
Part 2	Test methods for overall migration into olive oil by total immersion
Part 3	Test methods for overall migration into aqueous food simulants by total immersion
Part 4	Test methods for overall migration into olive oil by cell
Part 5	Test methods for overall migration into aqueous food simulants by cell
Part 6	Test methods for overall migration into olive oil using a pouch
Part 7	Test methods for overall migration into aqueous food simulants using a pouch
Part 8	Test methods for overall migration into olive oil by article filling
Part 9	Test methods for overall migration into aqueous simulants by article filling
Part 10	Test methods for overall migration into olive oil (modified method for use in cases where incomplete extraction of olive oil occurs)
Part 11	Test methods for overall migration into mixtures of ^{14}C-labelled synthetic triglyceride
Part 12	Test methods for overall migration at low temperatures
Part 13	Test method for overall migration at high temperatures
Part 14	Test methods for 'substitute tests' for overall migration from plastics intended to come into contact with fatty foodstuffs using test media iso-octane and 95 % ethanol

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

1 Scope

This European Standard specifies two alternative test methods, in the sense of an extraction test with a 'more severe' test character, for the assessment of the overall migration into fatty food simulants.

Method A is based on the determination of the extraction of migrateable substances from plastics which are intended to come into contact with foodstuffs, by total immersion in non-polar, iso-octane, and/or polar, ethanol, solvents depending on the polarity of the packaging material. According to results obtained by this method (see [1], [2], [3], [4], [5]) and taking physio-chemical considerations into account, the obtained extraction efficiency has, generally, been found to be equivalent to or higher than overall migration results obtained under the test conditions, 10 days at 40 °C, 2 h at 70 °C, 1 h at 100 °C, 30 min at 121 °C and 30 min at 130 °C.

To ensure as complete as possible extraction of the potential migrants, a strong interaction, e.g. swelling, of the sample by the extraction solvent is necessary. For this purpose, iso-octane is used as an extraction solvent for plastics materials and articles containing non polar food contact layers, such as polyolefins. For test samples made from polar food contact plastics such as polyamide and polyethylene terephthalate, 95 % (v/v) aqueous ethanol is used. For polystyrenes, plasticized polyvinyl chloride and other polymers where the identification or polarity of the polymer is not clear, two parallel extraction tests should be conducted using both of the proposed extraction solvents and taking the higher value obtained as the relevant result.

NOTE 1 In case of multilayer structures such as plastics laminates and co-extruded plastics, the nature of the food contact layer determines the selection of the extraction solvent(s).

This test method should only be applied to flexible packagings which are less than 300 µm in thickness. When the result does not exceed the allowed overall migration limit then the material can be considered to be in compliance with EC regulations. If the test result exceeds the allowed overall migration limit the following options may be applied chronologically with respect to further migration testing:

1) single-sided extraction test using a cell, if technically feasible (see clause 4 Method B of this standard);

2) conventional migration test using olive oil or other fatty food simulants;

NOTE 2 The overall migration limit is specified in Commission Directive 90/128/EEC [7] and the conditions of test in Council Directive 82/711/EEC [8] and its subsequent amendments, [9], [10].

Method B is applicable in those cases where the total immersion test, EN 1186-15 Method A, yields total extraction values that exceed the overall migration or may be technically unsuitable, i.e. in the case of multilayer structures, such as plastics laminates and co-extruded films. This test method should primarily only be applied to flexible packagings with a physical barrier layer (for instance of aluminium or other material to prevent penetrative loss of extraction solvent) and which have a thinner food contact layer than 300 µm. If the result does not exceed the allowed overall migration limit then the material can be considered to be in compliance with EC regulations. If the test result exceeds the allowed overall migration limit then the following option may be applied with respect to further migration testing:

- conventional migration test using olive oil or other fatty food simulants.

NOTE 3 Methods A and B are not applicable to test materials intended for applications over 130 °C.

NOTE 4 Test materials intended for applications over 70 °C should be checked for their physical suitability at the intended time and temperature of use.

2 Normative references

This European Standard incorporates by dated and undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to and revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 1186-1:2002, *Materials and articles in contact with foodstuffs – Plastics – Part 1: Guide to the selection of conditions and test methods for overall migration*.

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

ISO 4788, *Laboratory glassware - Graduated measuring cylinders*.

3 Method A
Alternative test method to migration into fatty food simulants by rapid extraction into iso-octane and/or 95 % ethanol by total immersion

3.1 Principle

The migrateable substances extracted from a sample of the plastics is determined as the mass of non-volatile residue after evaporation of the solvent following immersion. Test specimens of at least 1 dm² (single side considered) are immersed in the extraction solvent for 24 h at 40 °C or 50 °C and then removed. The extraction solvent is evaporated to dryness, the mass of the non-volatile residue is determined and expressed as milligrams per square decimetre of surface area of the test specimen. The measured value is compared to the EC-official overall migration limit and taking the analytical tolerance of this method (± 1 mg/dm²) into account.

3.2 Reagents

NOTE For details of preparation and quality of these reagents, see clause 5 of EN 1186-1:2002.

3.2.1 Ethanol 95 % (v/v) in aqueous solution.

3.2.2 Iso-octane (2,2,4-trimethylpentane)

NOTE The extraction solvents given in 3.2.1 and 3.2.2 are selected according to the nature of the polymer test sample as given by Table 1, see 3.5.1.