SLOVENSKI STANDARD
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Nadomešča:
SIST EN 1186-14:2003
SIST EN 1186-15:2003
SIST EN 1186-3:2002
SIST EN 1186-5:2002
SIST EN 1186-7:2002
SIST EN 1186-9:2002

Materiali in predmeti v stiku z živili - Plastika - 3. del: Preskusne metode za celotno migracijo v modelno izparljivo raztopino

Materials and articles in contact with foodstuffs - Plastics - Part 3: Test methods for overall migration in evaporable simulants

Werkstoffe und Gegenstände in Kontakt mit Lebensmitteln - Kunststoffe - Teil 3: Prüfverfahren für die Gesamtmigration in verdampfbaren Simulanzien

Matériaux et objets en contact avec les denrées alimentaires - Matière plastique - Partie 3 : Méthodes d'essai pour la migration globale dans les simulants évaporables

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EUROPEAN STANDARD

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English Version

Materials and articles in contact with foodstuffs - Plastics - Part 3: Test methods for overall migration in evaporable simulants

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

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European foreword

This document (EN 1186-3:2022) has been prepared by Technical Committee CEN/TC 194 “Utensils in contact with food”, 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of an identical text or by endorsement, at the latest by February 2023, and conflicting national standards shall be withdrawn at the latest by February 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 1186-3:2002, EN 1186-5:2002, EN 1186-7:2002, EN 1186-9:2002, EN 1186-14:2002 and EN 1186-15:2002.

This document implements European Commission Regulation on plastic materials and articles intended to come into contact with food with regards to the determination of the overall migration in food simulants. This regulatory text is subject to change; therefore, it is strongly recommended that users of this document refer to the latest relevant published regulatory texts (to be found on the European Commission website) before commencement of any of the tests described in this document.

In comparison with the previous editions, the following technical modifications have been made:

— removed the regulatory provisions put in the document to avoid the document being obsolete after an update of regulation;

— adapted the method of test to the new conditions defined in the regulation;

— combined in one document the 6 previous standards that use evaporable simulants and which are based on the same principle of measuring.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

1 Scope

This document specifies methods for measuring overall migration of plastic materials and articles intended to come into contact with foodstuffs by contacting test specimens with evaporable food simulants at temperatures greater than or equal to 4 °C and not exceeding the reflux temperature.

The overall migration from a sample of the plastics is determined as the loss in mass of non-volatile substances expressed:

— per unit surface area; or

— per kg of food simulant; or

— per article

after contact with a food simulant under defined conditions.

According to the type of materials or shape of articles, contact with the food simulant is carried out on a single surface (pouch, cell, filling) or by immersion.

This document does not cover the interpretation of the results which is expected to account for regulatory requirements.

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.

ISO 648, *Laboratory glassware — Single-volume pipettes*

3 Terms and definitions

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

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
ready-to-use article
article as sold that can be used with minimal if any preparation

3.2
sample
material or article under test

3.3
test specimen
part of the sample undergoing a measurement during the test

3.4
piece
portion of a test specimen

3.5
conventional oven
thermostatically controlled heat chamber where the air within is heated and this heat is then transferred to the food through the plastic, as opposed to a microwave oven where the food itself is heated directly by the microwave's irradiation

3.6
fillable pouch
receptacle of a defined size, manufactured in the film under test and which, once filled with food simulant, exposes the side of the film to be in contact with foodstuffs to such a food simulant or to a test medium

3.7
reverse pouch
pouch manufactured such that the surface to be in contact with foodstuffs is the outer surface

Note 1 to entry: All sides are sealed to prevent inner surfaces from coming into contact with the food simulant. The reverse pouch is to be completely immersed in the food simulant or in the test medium.

3.8
cell
device in which the film under test can be mounted and which, when assembled and filled with food simulant, exposes the side of the film to be in contact with foodstuffs to such a food simulant or to a test medium

3.9
food simulant
test medium imitating food, in its behaviour food simulant mimics migration for food contact materials

3.10
evaporable simulants
alternative and screening simulants/solvents, e.g. isooctane and 95 % ethanol

Note 1 to entry: Aqueous food simulants defined in the regulation.

4 Test method

4.1 Principle

4.1.1 General

The overall migration of a material or a ready-to-use article made of plastic in contact with foods, is determined by putting test specimens in contact with evaporable food simulants in test conditions chosen on the basis of the worst-case scenario of use and by weighing the dry residue of the evaporated food simulant.

The conditions of exposure of the test specimens are between 4 °C up to 100 °C or to the reflux temperature.

According to the type of sample, the tests are conducted based on one of the contacting methods given in 4.1.2 to 4.1.6.

4.1.2 Method 1: total immersion (in conventional oven or at reflux)

4.1.2.1 General

Test specimens of known surface are immersed in the food simulant. This method is most suitable for samples in the form of films and sheets, but can also be applied to a wide range of articles or containers from which test specimens of suitable size can be cut.

4.1.2.2 Method 1a: total immersion in conventional oven

This method is suitable for tests between 4 °C up to 100 °C or to reflux temperature.

4.1.2.3 Method 1b: total immersion at reflux

This method is only suitable for tests at the boiling point of the food simulant and generally for short periods of time (for example, up to 4 h).

4.1.3 Method 2: cell

Test specimens of known surface are placed in contact with the food simulant in a cell. This method is most suitable for plastics in the form of films or sheets in which only one side is to be in contact with foodstuffs (printed multi-layer materials, etc.).

4.1.4 Method 3: fillable pouch

Test specimens of known surface and in the form of pouches are filled with the food simulant; this method is suitable for plastics in the form of films or sheets in which the surface to be in contact with foodstuffs (printed, multi-layer materials) can be sealed by applying heat or pressure, to form a pouch.

4.1.5 Method 4: reverse pouch

Test specimens of known surface and in the form of reverse pouches are immersed in the food simulant; this method is suitable for plastics in the form of films or sheets in which the surfaces can be sealed by applying heat or pressure to form reverse pouches. If the sample material allows, the reverse pouches shall be used instead of the fillable pouches when the temperature of the food simulant is greater than or equal to 70 °C, because of the pressure of the food simulant that can break the sealing of the pouches at high temperatures.

4.1.6 Method 5: filling a container

Test specimens of known surface are filled in with the food simulant; this method is most suitable for plastics in the form of fillable containers and articles.

4.2 Reagents

The reagents specified hereinafter shall be evaporable at atmospheric pressure and at a temperature less than or equal to 105 °C. The non-volatile residue of a food simulant shall be less than 5 mg/l when evaporated to dryness and desiccated until a constant mass is obtained at a temperature between 105 °C and 110 °C.

— Purified water: distilled water or water treated by ions exchange resin;

— 3 % acetic acid (w/V) in aqueous solution: The solution is prepared by diluting 30 g of glacial acetic acid (28,6 ml with ρ = 1,05) and completed with purified water to obtain one litre of solution of 3 % acetic acid(w/V);

— Hydroalcoholic solutions (10 %, 20 %, 50 % and 95 % (V/V)) are prepared according to Annex A, Table A.1;

— Iso-octane.

Other kinds of evaporable liquids can be used as simulants of foods if permitted by the regulation.

4.3 Materials and apparatus

4.3.1 General

Equipment used for testing shall not have properties which interfere with the measurements. The total mass transfers by the equipment including the mass residue coming from the simulant shall be less than 5 mg/l of food simulant. The equipment shall be suitably cleaned.

4.3.2 Common materials and apparatus for all methods

4.3.2.1 Analytical balance where it can be read at least 0,1 mg.

4.3.2.2 Thermostatically controlled oven, incubator or refrigerator, capable of maintaining the temperature within the tolerance limits specified in A.2.

4.3.2.3 Glass, glass ceramic, ceramic, stainless steel, nickel, aluminium, platinum, platinum alloy, gold dishes, 50 mm to 90 mm diameter and maximum mass 100 g, for evaporation of food simulants and weighing of residues. Glass, glass ceramic or ceramic dishes may be used provided that the surface characteristics are such that the masses of the dishes after evaporation of any specified food simulants followed by conditioning in the desiccator used are stable within ±0,5 mg.

NOTE Not all materials are suitable for all evaporable simulants.

4.3.2.4 Steam bath, hot plate, distillation apparatus or rotary evaporator for evaporation of food simulant at the end of test period.

4.3.2.5 Desiccator with, for example, anhydrous calcium chloride or silica gel.

4.3.2.6 Lint-free cloth or soft brush or pure compressed air generator.

4.3.3 Common materials for methods other than filling a container

4.3.3.1 Cutting slab, clean smooth glass, metal or plastic slab of suitable area to prepare test specimens.

4.3.3.2 Blunt-nosed tweezers, for example made of stainless steel.

4.3.3.3 Cutting implement: scalpel, scissors, sharp knife or other suitable implement.

4.3.3.4 Cutting templates measuring (100 mm ± 0,2 mm) × (100 mm ± 0,2 mm).

4.3.3.5 Tool for measuring length, when it can be read 1 mm.

4.3.3.6 Glass containers for containing the food simulant and test specimens, for example test containers, ground neck, with an internal diameter of approximately 35 mm and length in the range of 100 mm to 200 mm, excluding the ground neck or ground-necked flasks of suitable size.

4.3.3.7 Pipettes, 50 ml and 100 ml, conforming to the requirements of ISO 648 Class B or automatic pipettes of equivalent performances or measuring cylinders.

4.3.4 Materials for method 1a (total immersion in conventional oven)

4.3.4.1 Specimen supports, for example made of stainless steel, capable of holding and keeping the test pieces apart and at the same time ensuring complete contact with the food simulant.

4.3.4.2 Gauze, for example, fine stainless steel gauze, mesh size 1 mm, approximately 25 mm x 100 mm in size.

4.3.4.3 Glass rods, for example 2 mm to 3 mm in diameter and approximately 100 mm long, for insertion between the test pieces.

4.3.4.4 Glass beads, for example 2 mm to 3 mm in diameter.

4.3.5 Materials for method 1b (total immersion at reflux)

4.3.5.1 Ground-necked flasks of suitable size.

4.3.5.2 Condensers to fit the flasks.

4.3.5.3 Heating device for maintaining the food simulants at reflux temperature during exposure.

4.3.5.4 Glass filter, pore size 100 µm to 160 µm.

4.3.5.5 Device to prevent the test specimen to come in contact with the heated glass flask.

4.3.6 Materials for method 2 (cell)

Appropriate cells have the following requirements:

— minimum of 0,4 dm^2 of contact area for the test specimen;

— surface to volume ratio shall be between (1 to 2) cm^{-1} for the test specimen;

— blank value shall be less than 5 mg/l.

4.3.7 Materials for method 3 (fillable pouch) and method 4 (reverse pouch)

4.3.7.1 Heat or pressure sealing device, for use in forming pouches.

4.3.7.2 Pouch holder.

4.3.8 Materials for method 5 (filling a container)

Glass containers of suitable size.

4.4 Preparation of test specimens

4.4.1 General

The test specimens shall be clean and free from surface contamination (many plastics can readily attract dust due to static charges). Before preparing test specimens, remove any surface contamination from the sample by gently wiping it with a lint-free cloth, or by brushing with a soft brush or with a compressed air stream.

As a general rule, do not wash the test specimens with water or solvent. However, if the articles are accompanied by instructions for use intended for the user advising cleaning before use, these instructions should be followed for the test, unless they advise rubbing the article with oil: in this case, the instructions should not be followed insofar as the oil would be included in the overall migration.

Minimize handling of the samples and where necessary, wear cotton gloves.

For one measurement, use a sufficient number of materials or articles to provide a surface area of 1 dm^2. A surface area of 1 dm^2 and volume of 100 ml are recommended.

Use a sufficient number of test specimens to get a valid result. Three replicates are recommended.

Determine the surface area of each test specimen to the nearest 0,01 dm^2 and record.

If the result is to be expressed in mg/kg, determine the contact surface area and the volume of the article and record.

4.4.2 Preparation of test specimens and determination of the area in contact

4.4.2.1 Method 1: total immersion in conventional oven or at reflux

4.4.2.1.1 General

Cut out test specimens of 1 dm^2 ± 0,01 dm^2 using a cutting template. If this is not possible, cut out pieces suitable for obtaining test specimens having a surface area of approximately 1 dm^2.

Ensure that the test pieces are well separated and that their surfaces are freely exposed to the food simulant during the test, using gauze, glass rods and/or specimen holders as required.

If the area of the edges of the test specimen exceeds 10 % of the area of the test specimen measured, this is incorporated in the area calculation.

4.4.2.1.2 Films and sheets

For the method in a conventional oven, cut each test specimen into four pieces (or into an appropriate number) measuring approximately 25 mm × 100 mm by using the tool of 4.3.3.3. For the method at reflux, if necessary, cut each test specimen into smaller pieces.

4.4.2.1.3 Containers and other articles

Cut pieces from the walls of the container or article to give test specimens each approximately 1 dm^2 in surface area. For articles with individual surface areas less than 1 dm^2, use a sufficient number of articles to provide a surface of 1dm^2. Measure the dimensions of each test specimen to the nearest 1 mm, by using the tool of 4.3.3.5.

Calculate the surface area of each test specimen to the nearest 0,01 dm^2 and record. If necessary, cut each test specimen into smaller pieces to enable them to fit into the glass test containers. The test specimens or pieces are placed on the specimen holders or, if the test specimens are sufficiently rigid, they can be tested unsupported.

The number of cuttings should be as low as possible.

4.4.2.1.4 Articles of irregular shape

Select representative portions of the article, or multiples of the article for small articles, to give sufficient area of material to obtain test specimen (s). Surface area of each test specimen should be at least 1 dm^2. Measure only the surface area of the test specimens intended to come into contact with foodstuffs to the nearest 0,05 dm^2 using the Schlegel Method [5], the method described by Mieth and Hoekstra [6] or any other suitable method [7]. Record the surface area of each test specimen.

4.4.2.2 Method 2: cell

Lay the sample on the cutting slab with the surface to be in contact with the food simulant uppermost. Cut out a test specimen of suitable dimensions for the cell using the cutting implement.

4.4.2.3 Method 3: fillable pouch

Prepare a pouch suitable for obtaining an internal contact area of 2 dm^2 and containing a volume of approximately 100 ml of food simulant.