
Materiali in predmeti v stiku z živilni - Plastične mase - 3. del: Preskusne metode za celotno migracijo v vodne modelne raztopine s popolno potopitvijo

Materials and articles in contact with foodstuffs - Plastics - Part 3: Test methods for overall migration into aqueous simulants by total immersion

Werkstoffe und Gegenstände in Kontakt mit Lebensmitteln - Kunststoffe - Teil 3: Prüfverfahren der Gesamtmigration in wäßrige Prüflebensmittel durch völliges Eintauchen

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Matériaux et objets en contact avec les denrées alimentaires - Matière plastique - Partie 3: Méthodes d'essai pour la migration globale dans les liquides simulateurs aqueux par immersion

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English version

**Materials and articles in contact with foodstuffs -
Plastics - Part 3 : Test methods for overall
migration into aqueous simulants by total
immersion**

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alimentaires - Matière plastique - Partie 3 :
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MINISTRSTVO ZA ZNANOST IN TEHNOLOGIJO
Urad RS za standardizacijo in meroslovje
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Foreword

This Part of this European Prestandard has been prepared by a Subcommittee (SC1) of TC194 'Utensils in contact with food' as one of a series of methods of test for plastics materials and articles in contact with foodstuffs.

Further Parts of this prestandard have been prepared, and others are in preparation, concerned with the determination of overall migration from plastics materials into food simulants.

Their titles are as follows:

- ENV 1186-1 Guide to the selection of conditions and test methods for overall migration
- ENV 1186-2 Test methods for overall migration into olive oil simulants by total immersion
- ENV 1186-4 Test methods for overall migration into olive oil by cell
- ENV 1186-5 Test methods for overall migration into aqueous food simulants by cell
- ENV 1186-6 Test methods for overall migration into olive oil using a pouch
- ENV 1186-7 Test methods for overall migration into aqueous food simulants using a pouch
- ENV 1186-8 Test methods for overall migration into olive oil by article filling
- ENV 1186-9 Test methods for overall migration into aqueous simulants by article filling
- ENV 1186-10 Test methods for overall migration into olive oil (modified method for use in cases where incomplete extraction of olive oil occurs)

Further Parts in preparation are as follows:

- ENV 1186-11 Test methods for overall migration into mixtures of ¹⁴C-labelled synthetic triglyceride
- ENV 1186-12 Test methods for overall migration at low temperatures
- ENV 1186-13 Test methods for overall migration at high temperatures

ENV 1186-3 should be read in conjunction with ENV 1186-1.

According to the CEN/CENELEC Internal Regulations, the following countries are bound to announce this European prestandard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom.

1 Scope

This Part of this European Prestandard describes a test method for the determination of the overall migration into aqueous based food simulants from plastics which are intended to come into contact with foodstuffs, by total immersion in aqueous food simulant for 10 days, 24 h or 2 h at 40 °C or for 2 h at 70 °C.

This method is most suitable for plastics in the form of films and sheets, but can be applied to a wide range of articles or containers from which test pieces of suitable size can be cut.

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.

- ISO 648:1977 Laboratory glassware - One mark pipettes
- ISO 4788:1980 Laboratory glassware - Graduated measuring cylinders
- ISO 8442:1988 Stainless steel and silver plated table cutlery ¹⁾
- ENV 1186-1 Guide to the selection of conditions and test methods for overall migration
- prEN 10088 Stainless steels ²⁾

3 Principle

The overall migration of non-volatile substances from a sample of the plastics is determined as the mass of non-volatile residue after evaporation of the food simulant following immersion.

The selection of the conditions of test will be determined by the conditions of use, see clause 3 of ENV 1186-1.

Test specimens of approximately 1 dm², see clause 3 of ENV 1186-1, are immersed in the food simulant for 10 days, 24 h or 2 h at 40 °C or for 2 h at 70 °C then removed. The food simulant 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 specimen.

- 1) A European Standard for stainless steel and silver plated cutlery is in course of preparation.
- 2) In course of preparation

Overall migration is reported as the mean of three determinations on separate test specimens.

4 Reagents

NOTE: For details of preparation and quality of these reagents, see clause 4 of ENV 1186-1.

- 4.1 Distilled water or water of equivalent quality (simulant A)
- 4.2 Acetic acid 3 % (w/v) in aqueous solution (simulant B)
- 4.3 Ethanol 15 % (v/v) in aqueous solution (simulant C)
- 4.4 Alcoholic simulants for liquids or beverages of an alcoholic strength exceeding 15 % (v/v).

NOTE: In the case of materials and articles intended to come into contact with liquids or beverages of an alcoholic strength exceeding 15 % (v/v), the test may be carried out with aqueous solutions of ethanol of a similar strength.

5 Apparatus

- 5.1 Cutting slab, clean smooth glass, metal or plastics slab of suitable area to prepare test specimens, 250 mm x 250 mm is suitable.
- 5.2 Tweezers, stainless steel, blunt-nosed.
- 5.3 Cutting implement, scalpel, scissors or sharp knife or other suitable device.
- 5.4 Metal template, 100 mm \pm 0,2 mm x 100 mm \pm 0,2 mm (square).
- 5.5 Rule, 25 mm \pm 1 mm wide.
- 5.6 Rule, graduated in mm, and with an accuracy of 0,1 mm.
- 5.7 Analytical balance capable determining a change in mass of 0,1 mg.
- 5.8 Specimen supports, constructed of stainless steel with cross arms attached by welding or silver soldering, or of glass. Stainless steel X4 CrNi 18 10 according to prEN 10088 or of composition, chromium 17 %, nickel 9 %, carbon 0,04 %, is suitable. Before initial use thoroughly clean the stainless steel supports. The use of a degreasing solvent and then with dilute nitric acid has been found to be suitable. For the aqueous acetic acid food simulant, use supports constructed out of glass, as there is a tendency for the acetic acid to corrode stainless steel supports, particularly if the joints are silver soldered. However stainless steel supports may be used for acetic acid if it can be demonstrated that they do not contribute to the residue. Assess all supports to ensure that they do not contribute significantly to the residue.

NOTE: The method has been written for the supports shown in figure 1 of ENV 1186-1 which have been found to be suitable for holding thin film and sheet test pieces. However other supports may be used providing they are capable of holding and keeping the test pieces apart and at the same time ensuring complete contact with the simulant. For rigid samples, supports with a single cross arm may be used.

- 5.9 Gauze, pieces of fine stainless steel gauze, with a mesh size of 1 mm have been found to be suitable, approximately 25 mm x 100 mm or, glass rods, 2 mm to 3 mm in diameter and approximately 100 mm long to be used with the acetic acid food simulant, for insertion between the test pieces. Before initial use thoroughly clean the gauze, first with a degreasing solvent and then with dilute nitric acid.
- 5.10 Glass tubes, ground neck, for retaining the food simulant and test specimens. Tubes with an internal diameter of approximately 35 mm and length of in the range of 100 mm to 200 mm, excluding the ground neck (see 5.2 of ENV 1186-1) have been found to be satisfactory.
- 5.11 Glass beads, 2 mm to 3 mm diameter or glass rods, 2 mm to 3 mm in diameter and approximately 100 mm long (see 5.2 of ENV 1186-1).
- 5.12 Thermostatically controlled oven or incubator capable of maintaining a temperature of $40\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ and $70\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$.
- 5.13 Dishes, stainless steel, nickel, platinum, platinum alloy, gold 50 mm to 90 mm diameter and maximum weight 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 weights of the dishes after evaporation of any specified food simulants followed by conditioning in the desiccator used achieves a constancy of $\pm 0,5$ mg. Stainless steel and nickel dishes are suitable only for distilled water and ethanol solutions. Glass, glass ceramic, glazed ceramic, platinum or, platinum alloy or gold dishes are suitable for all three simulants.
- 5.14 Steam bath, hot plate, distillation apparatus or rotary evaporator for evaporation of food simulant at the end of test period.
- 5.15 Desiccator with anhydrous calcium chloride or self indicating silica gel.
- 5.16 Measuring cylinder, 100 ml, complying with the minimum requirements of ISO 4788.

6 Preparation of test specimens

It is essential that test specimens are 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. Under no circumstances wash the sample with water or solvent. If it is specified in the instructions for use of the article that it should be washed

or cleaned before use see 6.1 of ENV 1186-1. Minimise handling of the samples and where necessary, wear cotton gloves.

To ensure that test pieces are well separated and that the surfaces are freely exposed to the food simulant during the period of the test, for thin films, insert a piece of fine stainless steel gauze, or glass rods with the acetic acid simulant, between the test pieces or for thick samples not placed on the supports, insert glass rods between the test pieces after immersion in the food simulant. Where specimen supports are used, label the supports with a tag bearing the test specimen identification.

6.2 Number of test specimens

Three test specimens are required for samples, in the form of thin films, sheet, containers or similar articles. Five test specimens, similar dimensionally one to another, are required for samples of articles of irregular shape.

These test specimens are utilized as follows:

- a) Three test specimens for the migration test;
- b) Two test specimens for determination of the surface area, in the case of samples of irregular shape (6.5).

6.3 Thin films and sheet materials

Lay the sample on the cutting slab (5.1) and cut the test specimens of 1 dm² (see 6.3 of ENV 1186-1), using the 100 mm x 100 mm template (5.4). Check, using the rule (5.5), that the dimensions of the specimen are within the specified tolerance (± 1 mm).

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Cut each test specimen into four test pieces 25 mm x 100 mm using the rule (5.5). Assemble one test specimen onto the support by piercing suitable holes in the test pieces and placing two test pieces on each side of the cross arms of the support. Repeat this procedure for all remaining test specimens.

6.4 Containers and other articles

Cut sections from the walls of the container or article to give test specimens each of area approximately 1 dm². For articles with individual areas less than 1 dm², use a number of articles to provide each test specimen. Measure the dimensions of each test specimen to the nearest 1 mm, using the rule. Measure only the surface area of the sample which is intended to come into contact with foodstuffs, i.e. cut edges and any surfaces not intended to come into contact with foodstuffs are ignored (see 6.3 of ENV 1186-1). Calculate the area of each test specimen to the nearest 0,01 dm² and record. If necessary, cut each test specimen into smaller pieces to enable them to fit into the glass tubes (5.10). The test specimens or pieces are placed on the specimen supports if these are appropriate or, if the test specimens or pieces are sufficiently rigid, they can be tested unsupported.