
Materiali in predmeti v stiku z živilni - Plastične mase - 5. del: Preskusne metode za celotno migracijo v vodne modelne raztopine z migracijsko celico

Materials and articles in contact with foodstuffs - Plastics - Part 5: Test methods for overall migration into aqueous food simulants by cell

Werkstoffe und Gegenstände in Kontakt mit Lebensmitteln - Kunststoffe - Teil 5: Prüfverfahren der Gesamtmigration in wäßrige Prüflebensmittel-Zellen

Matériaux et objets en contact avec les denrées alimentaires - Matière plastique - Partie 5: Méthodes d'essai pour la migration globale dans les liquides simulateurs aqueux en cellule

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EUROPEAN PRESTANDARD

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English version

**Materials and articles in contact with foodstuffs -
Plastics - Part 5 : Test methods for overall
migration into aqueous food simulant by cell**

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Matériaux et objets en contact avec les denrées
alimentaires - Matière plastique - Partie 5 :
Méthodes d'essai pour la migration globale dans
les liquides simulateurs aqueux en cellule

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MINISTRSTVO ZA ZNANOST IN TEHNOLOGIJO
Urad RS za standardizacijo in meroslovje
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PREVZET PO METODI RAZGLASITVE

-01- 1997

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European Committee for Standardization
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Europäisches Komitee für Normung

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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 by total immersion
- ENV 1186-3 Test methods for overall migration into aqueous food simulants by total immersion
- ENV 1186-4 Test methods for overall migration into olive oil 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 1186-5 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 method of test for the determination of the overall migration from one surface only of plastics in the form of sheet and film, which are intended to come into contact with foodstuffs, into aqueous based food simulants, by exposure in a standard cell 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 is particularly applicable to those materials consisting of more than one layer or of surfaces that differ in their migration characteristics, which must be tested with the food simulant in contact only with the surface which is intended to come into contact with foodstuffs.

2 Normative references

This European Prestandard 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 Prestandard 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

ENV 1186-1 Guide to the selection of conditions and test methods for overall migration

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.

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

One surface of the test specimen of area 2.5 dm² is exposed in a standard cell to the food simulant for either 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.

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

4 Reagents

NOTE: For details of the preparation and purity 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 Rule, graduated in mm, and with an accuracy of 0,1 mm.
- 5.5 Analytical balance capable of determining a change in mass of 0,1 mg.
- 5.6 Standard cells, type A as shown in Annex D figure 3 of ENV 1186-1, either the all aluminium (anodised) cells or the cells with the stainless steel (316 grade) lids and rings, are suitable for the water and aqueous ethanol food simulants. For the aqueous acetic acid food simulant the cells with the stainless steel lids and rings must be used. The internal diameter of the rib of the sealing ring shall be 178,4 mm \pm 0,1 mm, to give an area of the test specimen exposed to the food simulant of 2,5 dm².

NOTE: The standard cells are constructed with a rubber mat in the base plate. When using the cells with either the water or aqueous ethanol food simulants it is advised that a disc of aluminium foil is placed on the mat before inserting the test specimen. For the aqueous acetic acid food simulant use a disc of PTFE or other suitable material which is inert to acetic acid. The use of these discs will prevent any substances from the mat influencing the migration result.

For details of equivalent cells see 5.3 of ENV 1186-1.

- 5.7 Pipettes, complying with the minimum requirements of ISO 648, 50 ml and 100 ml.

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5.8 Glass tubes, ground neck, and stoppers, for retaining the food simulant. Tubes with an internal diameter of approximately 35 mm and length of approximately 100 mm to 200 mm, excluding the ground neck (see 5.2 of ENV 1186-1) have been found to be satisfactory.

5.9 Thermostatically controlled oven or incubator capable of maintaining a temperature of $40\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ and $70\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$.

5.10 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 $\pm 0,5\text{ mg}$. Stainless steel and nickel dishes are suitable only for distilled water and ethanol solutions. Glass, glass ceramic, glazed ceramic, platinum, platinum alloy or gold dishes are suitable for all three simulants.

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

5.12 Desiccator with anhydrous calcium chloride or self indicating silica gel.

5.13 Measuring cylinders, 250 ml, complying with the minimum requirements of ISO 4788.

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6 Preparation of test specimens

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6.1 General <https://standards.iteh.ai/catalog/standards/sist/3b30f12c-8cff-4f22-a8da-1dc3ba48dc52/sist-env-1186-5-1997>

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.

6.2 Number of test specimens

Three test specimens are required for samples, in the form of thin films, sheet, and flat sections cut from containers or similar articles.

6.3 Cutting test specimens

Lay the sample on the cutting slab (5.1) with the surface to be in contact with the food simulant uppermost. Take the ring from the standard cell (5.6) and place on the surface of the sample. Cut out the test specimen by cutting round the outer edge of the ring, using the cutting implement (5.3).

7 Procedure

7.1 Exposure to food simulant

Take three standard cells (5.6), mark these for identification purposes. Place in the thermostatically controlled oven or incubator (5.9), which is set at the selected test temperature and leave until the test temperature has been attained.

Take three glass tubes (5.8) measure by measuring cylinder 125 mL \pm 2 ml of the food simulant into each tube, stopper the tube and mark the level of the liquid on the outside, together with a mark for identification. If the evaporation method is to be used (7.2.2) measure into a further two tubes by measuring cylinder 185 mL \pm 2 ml of the food simulant, to provide blanks. If the distillation method (7.2.3) is to be used measure into a further two tubes by measuring cylinder 125 mL \pm 2 ml of the food simulant to provide blanks.

Mark the liquid level on the outside of each tube with a suitable marker.

Place the five tubes in the thermostatically controlled oven or incubator, set at the test temperature (40 °C or 70 °C), and leave until the test temperature has been attained.

Remove the cells from the thermostatically controlled oven or incubator, dismantle and place on the base of each cell one of the test specimens. Reassemble the cells, ensuring that the clamping screw wheel is well tightened down.

Remove three tubes containing 125 ml of the food simulant from the thermostatically controlled oven or incubator and transfer the food simulant from each tube to each of the test cells through the filler hole. Replace the filler plug and return the test cells to the thermostatically controlled oven or incubator, set at the test temperature. This part of the operation should be carried out in the minimum time to prevent undue heat loss from the cells and simulants.

Observe the temperature, leave the cells for a test period of 240 0 h
+5
+0,5 +5
24 0 h or 120 0 min, after the air bath of the thermostatically controlled oven or incubator has reached a temperature within 1 °C of the set temperature.

Take the cells and the two tubes containing the blank simulants from the thermostatically controlled oven or incubator.

Transfer by a 50 ml or 100 ml pipette the simulant from each of the three cells into the three tubes, check the level of simulant in each, if this has fallen to more than 10 mm below the mark, repeat the test with fresh test pieces. 90 % of the original volume of simulant must be recovered.

Rinse each cell twice with 20 mL \pm 2 ml of simulant, add these rinses to the respective tubes.