



SLOVENSKI STANDARD

SIST ENV 1186-7:1997

01-januar-1997

Materiali in predmeti v stiku z živilni - Plastične mase - 7. del: Preskusne metode za celotno migracijo v vodne modelne raztopine z vrečko

Materials and articles in contact with foodstuffs - Plastics - Part 7: Test methods for overall migration into aqueous simulants using a pouch

Werkstoffe und Gegenstände in Kontakt mit Lebensmitteln - Kunststoffe - Teil 7: Prüfverfahren der Gesamtmigration in wäßrige Prüflebensmitteln mit einem Beutel

Matériaux et objets en contact avec les denrées alimentaires - Matière plastique - Partie 7: Méthodes d'essai pour la migration globale dans les liquides simulateurs aqueux à l'aide d'un sachet

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EUROPEAN PRESTANDARD

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English version

**Materials and articles in contact with foodstuffs -
Plastics - Part 7 : Test methods for overall
migration into aqueous simulants using a pouch**

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Matériaux et objets en contact avec les denrées
alimentaires - Matière plastique - Partie 7 :
Méthodes d'essai pour la migration globale dans
les liquides simulateurs aqueux à l'aide d'un
sachet

Werkstoffe und Gegenstände in Kontakt mit
Lebensmitteln - Kunststoffe - Teil 7 :
Prüfverfahren der Gesamtmigration in wässrigen
Prüflebensmittel mit einem Beutel

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REPUBLIKA SLOVENIJA
MINISTRSTVO ZA ZNANOST IN TEHNOLOGIJO
Urad RS za standardizacijo in meroslovje
LJUBLJANA

SIST... ENV 1186-7 ...
PREVZET PO METODI RAZGLASITVE

-01- 1997

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CEN

European Committee for Standardization
Comité Européen de Normalisation
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 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 1186-5 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 1186-8 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 1186-7 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 film and sheet, which is intended to come into contact with foodstuffs, by forming the plastics film or sheet into standard pouches and exposure to the aqueous food simulant for 10 days, 24 h or 2 h at 40 °C or for 2 h at 70 °C.

A standard pouch is a pouch with the dimensions as described in 6.2.

This method is most suitable for plastics in the form of films and sheets which are sealable by heat or pressure. The test is particularly applicable to those materials consisting of more than one layer, which must be tested with the food simulant in contact only with the surface which is intended to be in contact with the 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.

Test specimens in the form of pouches are filled with the aqueous food simulant for the test period of 10 days, 24 h or 2 h at 40 °C or for 2 h at 70 °C. 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 Metal template 120 mm \pm 1 mm x 120 mm \pm 1 mm (square)
- 5.6 Analytical balance capable of determining a change in mass of 0,1 mg.
- 5.7 Pouch holder, the example shown in figure A.1 has been shown to be suitable, constructed from aluminium or other suitable material or an equivalent holder, plus clips to secure corners of pouches.
- 5.8 Pipettes, complying with the minimum requirements of ISO 648, 50 ml and 100 ml.
- 5.9 Glass tubes, ground neck, and stoppers, for retaining the food simulant and test specimens. Tubes with an internal diameter of approximately 35 mm and length 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.
- 5.10 Thermostatically controlled oven or incubator capable of maintaining a temperature of 40 °C \pm 1 °C and 70 °C \pm 2 °C.
- 5.11 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, platinum alloy or gold dishes are suitable for all three simulants.

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

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

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

5.15 Measuring cylinders, 100ml, complying with the minimum requirements of ISO 4788.

6 Preparation of test specimens

6.1 General

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.

6.3 Cutting and preparation of specimens

Lay the sample on the cutting slab (5.1) with the surface to be in contact with the food simulant uppermost and cut the test specimens using the 120 mm x 120 mm template (5.5).

Place pairs of the test pieces together with the surfaces to be in contact with the food simulant facing. Using the heat or pressure sealer, join to form pouches with four seals parallel to all four edges, 10 mm from the edge. Measure the distances between the inner edges of the seals to the nearest 1 mm and calculate the total surface area of the test specimen which will be exposed to the food simulant, to the nearest $0,01 \text{ dm}^2$. This shall be approximately 2 dm^2 . Using the cutting implement (5.3), remove excess film from the sealed area (to reduce area of film not directly exposed to food simulant whilst leaving enough to withstand the test conditions without leaking).

Mark each pouch for identification. Cut off one corner of the pouch to leave a hole sufficiently large to insert a 100 ml pipette.

7 Procedure

7.1 Exposure to food simulant

Take three glass tubes (5.9), measure by measuring cylinder 100 ml \pm 2 ml of the food simulant into each tube and stopper the tubes. If the evaporation method is to be used (7.2.2) measure into a further two tubes by measuring cylinder 120 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 100 ml \pm 2 ml of the food simulant to provide blanks. Place the five tubes and the pouch holder in the thermostatically controlled oven or incubator, set at the test temperature and leave until the test temperature has been attained.

Remove the pouch holder from the thermostatically controlled oven or incubator and place between the spacers the test specimen pouches.

Remove the three tubes containing the 100 ml of food simulant from the thermostatically controlled oven or incubator and into the three test specimens pouches pipette sufficient food simulant to just fill the pouch. This shall be about 100 ml, but for thick/semi-rigid materials the quantity will be less. Secure the open corner with a clip. If all the simulant is not used to fill the pouch, retain the tube and residual contents. Measure and record the volume of the residual food simulant. Measure and record the area of the pouch in contact with the simulant and the total external area of the pouch after trimming excess material. This part of the operation should be carried out in the minimum time to prevent undue heat loss.

Replace the pouch holder, containing the test specimen pouches, in the thermostatically controlled oven or incubator, set at the test temperature, leave for a test period of 240 \pm 5 h or 24 \pm 0,5 h or 120 \pm 5 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 pouch holder and the tubes containing the blank food simulant from the thermostatically controlled oven or incubator.

If an evident leak has occurred with more than one pouch, the test is invalid and must be repeated using fresh pouches.

If no evident leaks have occurred in at least three of the pouches, then proceed with 7.2.

NOTE: For plastics that lose simulant during the test period due to permeation through the plastic see 7.9 of ENV 1186-1.