SLOVENSKI STANDARD
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Materiali in predmeti v stiku z živili - Plastične mase - 1. del: Vodilo za izbiro pogojev in preskusnih metod za celotno migracijo

Materials and articles in contact with foodstuffs - Plastics - Part 1: Guide to the selection of conditions and test methods for overall migration

Werkstoffe und Gegenstände in Kontakt mit Lebensmitteln - Kunststoffe - Teil 1: Leitfaden für die Auswahl der Prüfbedingungen und Prüfverfahren für die Gesamtmigration

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Matériaux et objets en contact avec les denrées alimentaires - Matiere plastique - Partie 1: Guide pour le choix des conditions et des méthodes d'essai en matiere de migration globale

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Central Secretariat: rue de Stassart,36 B-1050 Brussels

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SIST ENV 1186-1:1997

Contents

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST ENV 1186-1:1997
https://standards.iteh.ai/catalog/standards/sist/40a6797e-3455-461c-9f21-5ca2d03a6ae9/sist-env-1186-1-1997

SIST ENV 1186-1:1997

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 1186-2 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

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ENV 1186-7 Test methods for overall migration into aqueous food simulants using a pouch

SIST ENV 1186-1:1997
https://standards.iteh.ai/catalog/standards/sist/40a6797e-3455-461c-9f21-5ac2d03a6ac9/sist-env-1186-1-1997

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 ^{14}C-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

Annexes A and B to this prestandard are normative where applicable.

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.

SIST ENV 1186-1:1997

0 Introduction

This prestandard is concerned with the testing required by the European Commission Directive relating to plastics materials and articles intended to come into contact with foodstuffs (90/128/EEC) (C.1).

Attention is drawn to Article 2 of the Council Directive of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (89/109/EEC) (C.2).

No single test method has been devised which can be used to determine overall migration, at all temperatures, in all food simulants. Indeed, owing to the practical difficulties inherent in testing with involatile extractants such as fats and the multitude of applications in which plastics articles come into contact with food, there are many methods and permitted variations to methods in this prestandard.

ENV 1186-1 is intended to give advice on the selection of the most appropriate test conditions and test method for a given application of a plastics article and should be read in its entirety before testing protocols are finalized. For most plastics articles methods in ENV 1186-2 to ENV 1186-10 are suitable, according to the form in which the article is tested. Subsequent Parts of this prestandard are intended to be used in conjunction with the methods in ENV 1186-2 to ENV 1186-10 for more difficult samples and at other temperatures.

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1 Scope

SIST ENV 1186-1:1997

This Part of this European Prestandard provides a guide to the selection of the appropriate conditions and methods of test for the determination of overall migration into food simulants from plastics which are intended to come into contact with foodstuffs.

2 Definitions

NOTE: For the purposes of this prestandard plastics are as described in Commission Directive 90/128/EEC Article 1, paragraph 3.

For the purposes of this prestandard the following definitions apply:

2.1 **final article:** article in its ready-for-use state or as sold.

2.2 **sample:** material or article under investigation.

2.3 **test specimen:** portion of the sample on which a test is performed.

2.4 **test piece:** portion of the test specimen.

SIST ENV 1186-1:1997

2.5 **conventional oven:** oven where the air within the oven 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 microwave irradiation.

2.6 **food simulant:** medium intended to simulate a foodstuff (see clause 4).

2.7 **overall migration; global migration:** mass of material transferred to the food simulant as determined by the relevant test method.

2.8 **standard pouch:** pouch of fixed dimensions which when filled with food simulant exposes a surface area of 2 dm^2 of plastic to the food simulant.

2.9 **reverse pouch:** pouch which is fabricated such that the surface intended to come into contact with foodstuffs is the outer surface. All of its sides are sealed to prevent the inner surfaces coming into contact with the food simulant. The reverse pouch is intended to be totally immersed in food simulant.

3 Conditions of test

3.1 General

The basic rules necessary for testing the migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs are laid down in Council Directive 82/711/EEC (C.3). This Directive specifies the test times and temperatures to be chosen according to conditions of contact in actual use. These are detailed in table A.1 for conditions of use up to 121° C. The Council Directive stated that where temperatures in use are above 121° C the test conditions should be in accordance with national laws.

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SIST ENV 1186-1:1997
https://standards.iteh.ai/catalog/standards/sist/40a6797e-3455-461c-9121-5ac2d03a6ae9/sist-env-1186-1-1997

NOTE: Since the approval of this Part by Subcommittee 1 of TC194 Council Directive 82/711/EEC has been amended by Commission Directive 93/9/EEC (C.4). This Directive includes amendment to the test conditions and temperatures to be chosen according to conditions of contact in actual use. The amended conditions are detailed in table A.2.

3.2 Testing where temperatures and times of use are known

Where the conditions of use, in terms of temperature(s) and time(s) of exposure, of the final article are known, it may be tested according to the test conditions specified in table A.1. If the final article is known to be subjected to a combination of conditions of use a combination of test conditions has to be employed as indicated in Chapter II clause 2 of the Annex of 82/711/EEC.

3.3 Testing where temperatures and times of use are not known

Many articles may be used at a variety of temperatures and for varying times, or their conditions of use may not be known. Where the plastics material or article may in actual use be employed under any conditions of contact time or temperature, only the 10 day tests at 40 °C and the 2 h tests at 70 °C are

SIST ENV 1186-1:1997

to be carried out with new specimens, these being conventionally regarded as the most stringent, according to clause 4 in Chapter II in the Annex of EC Directive 82/711/EEC. If the fat simulant is used, only the 10 day tests at 40 °C is to be carried out (see table A.1). This is considered to be sufficient testing to demonstrate compliance for use at all temperatures up to 121° C.

3.4 Testing at low temperatures

Testing with fats at 5 °C may lead to unreliable results if the fat partially solidifies or, in the case of the synthetic triglyceride mixture, totally solidifies. However, with olive oil and sunflower oil the test is usually without this problem at 10 °C. If the overall migration does not exceed the limit when tested at 10° C this indicates that it would not have exceeded the limit at 5 °C (see table A.1).

Alternatively a sunflower oil, which is free of components which solidify at the temperature of test (i.e. a "dewaxed" oil), may be used.

Testing by total immersion or in a standard cell or in an equivalent cell or in a standard pouch is practicable at low temperatures, although if a cell or pouch is used for the fat simulant, where a visual check on solidification is difficult, a dewaxed simulant should be used.

The method of test for the determination of overall migration at low temperatures (5 °C and 20 °C) is to be given in ENV 1186-12 [1)].

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3.5 Testing at high temperatures

When the test conditions for simulating exposure at temperatures above 121 °C have been agreed in a European Community Directive the methods for the determination at these temperatures will be incorporated in ENV 1186-13[1)].

3.6 Caps, gaskets, stoppers or similar sealing devices and lids

In many cases lids and closures may be expected to come into contact with foodstuffs and should be tested under similar conditions to the rest of the container. However in some high temperature applications the lid may only be exposed to water vapour and this condensed vapour may be returned to the bulk of the foodstuff (see 6.9).

3.7 Tubing, taps, valves, filters

Defining the time of exposure may be difficult for articles such as tubing, taps, valves, filters etc. as they may be in contact with flowing foodstuff. However, this exposure may be considered to be repeated brief contact for the purposes of migration testing. Such articles may be tested by repeated total immersion or by repeated filling, tubing may be stoppered with an inert stopper.

1) In preparation.

SIST ENV 1186-1:1997

4 Food simulants and reagents

The food simulants to be used in migration tests with a particular foodstuff or groups of foodstuffs are laid down in the annex of EC Directive 85/572/EEC (C.5). This is reproduced in table A.3.

4.1 Aqueous food simulants

The aqueous food simulants should be of the following quality:

- simulant A, distilled water or of equivalent quality;

- simulant B, acetic acid in aqueous solution. Council Directive 85/572/EEC specifies the use of 3 % w/v aqueous acetic acid. For the purposes of this prestandard this means a solution prepared by diluting 30 g of acetic acid with distilled water to a volume of 1 l;

- simulant C, ethanol 15 % (v/v) in aqueous solution.

Alcoholic simulants for liquids or beverages with an ethanol content greater than 15% (v/v). - according to Council Directive 85/572/EEC this test may be carried out with aqueous solutions of ethanol of a similar strength.

Each of the above food simulants should give a non-volatile residue of less than 5 mg/l, when evaporated to dryness and dried to constant weight at 105 °C to 110 °C.

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4.2 Fat simulants

SIST ENV 1186-1:1997
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The fat simulants are as follows:

- simulant D, rectified olive oil.

Also included in table A.3 are the characteristics of the rectified olive oil and of sunflower oil and the composition of the mixture of synthetic triglycerides. If for technical reasons connected with the method of analysis it is necessary to use different simulants, olive oil shall be replaced by a mixture of synthetic triglycerides or sunflower oil.

When these fatty food simulants are used to simulate some classes of food, reduction factors may be used as specified in EC Directive 85/572/EEC.

4.3 Simulating dry foods

According to EC Directive 85/572/EEC plastics intended to come into contact with dry food, such as cereals and dried eggs, need not be tested for overall migration.

4.4 Simulating all food types

Where a plastics article is intended for use in contact with all types of food it should be tested with all 3 aqueous simulants and the fat simulant without reduction factors.

SIST ENV 1186-1:1997

4.5 Reagents

Unless otherwise required, reagents shall be of analytical quality.

NOTE: Specifications for solid reagents, used as such in discrete quantities, may not address suitability for use in methods of analysis in this prestandard. Solid reagents may not be homogenous with respect to contaminants not addressed by specifications, therefore it may be necessary to demonstrate that such reagents are suitable for use.

5 Apparatus

5.1 Specimen supports

In the methods for determining overall migration by total immersion, cruciform specimen supports, see figure B.1, have been specified, but 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. An example of a type of support that has been used successfully, particularly for thick and very thin samples, which are wound around the support, is shown in figure B.2. This type of support when loaded with the specimens is exposed to the simulants in 100 ml beakers. The beaker is then covered with a watch glass. When using this support the ratio of 1 dm^2 of food contact area to 100 ml of simulant should be maintained where possible.

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5.2 Tubes, glass rods and glass beads

In several of the methods for determining overall migration by total immersion the samples are tested at a fixed ratio of surface area of test specimen to food simulant volume. In order to ensure that all parts of the test specimen are in contact with the food simulant, glass tubes of the appropriate diameter should be used. The dimensions of the suitable tubes are specified in the individual methods. However, minor adjustments to the level of the surface in the tubes may be made by adding glass rods or glass beads sufficient to ensure complete immersion of all of the surface of the test specimen. Again the dimensions of suitable glass rods and glass beads are specified in the individual methods.

SIST ENV 1186-1:1997
https://standards.iteh.ai/catalog/standards/sist/4f6a679e-9455-401c-9f2f-5de2d03a6ae9/sist-env-1186-1-1997

5.3 Cells

In the methods described in this European Prestandard, the availability of the standard cell, type A as shown in figure B.3, has been assumed. However alternative cells may be satisfactory if they produce results which, within experimental error, are equivalent to those produced with type A. These alternative cells should be of such design to give satisfactory performance, particularly freedom from leakage with all four food simulants to prevent contamination of the food simulant with non-volatile substances, and with minimum area of the test specimen not in direct contact with the food simulant. Examples of other cells that are available are type B and type C; these are shown in figures B.4 and B.5 respectively.

SIST ENV 1186-1:1997

5.4 Thermostatically controlled ovens or incubators

Experience has shown that close temperature control is essential to obtain repeatable results. Therefore care has to be exercised in selecting ovens or incubators to ensure that the temperature control is that specified in the methods throughout the volume of air encompassing the sample tubes, cells or pouches.

6 Samples and sample geometry

6.1 Samples

The samples taken for testing should be the final article, in its ready-for-use state. In some cases this may be impracticable and Commission Directive 90/128/EEC allows specimens to be taken from the material, article or where appropriate, specimens representative of this material or article may be used.

An example is where an article is filled with food at the time it is formed. In this case the test may be carried out on a test article prepared especially for testing purposes. This article has to be as representative as possible of the article in actual use.

A further example is where the sample to be tested is of inhomogeneous construction and is too large to be tested by filling and no flat surfaces can be cut from the sample for testing in the standard cell. In this case the test may be carried out on a test article prepared especially for testing purposes. This article has to be as representative as possible of the article in actual use.

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SIST ENV 1186-1:1997
https://standards.iteh.ai/catalog/standards/sist/40a6797e-3455-461c-9f21-5ac2d03a6ae9/sist-env-1186-1-1997

Where samples are taken at random from a production batch this should be indicated when reporting the result. The samples should be representative of normal production material.

Similarly if the sample was not a random sample, that is it was selected according to some other parameter (e.g. thickness variation) this should also be reported.

Samples may be inhomogeneous (e.g. varying in crystallinity or in molecular orientation), or of irregular shape or thickness (e.g. sections cut from bottles, trays, work surfaces, cutlery etc.) or so small that several samples are required to constitute a test specimen. Replicate samples as similar as possible to each other and proportionally representing the sample article should be tested and the sampling details should be included in the final report.

Samples should be clean and free from surface contamination; dust may be removed by wiping the sample with a lint-free cloth or brushing with a soft brush.

For some final articles there may be an instruction that they should be cleaned or treated with oils or other solvents before use. In these cases the samples should be tested both before and after the cleaning process and the results evaluated.

SIST ENV 1186-1:1997

6.2 Surface to volume ratio

Where the surface to volume ratio to be used in contact with food is known this should be used in the migration testing. An example of this is where a bottle or other container is intended to contain a specified volume of contents even if this does not completely fill the article. In this case the article should be tested with the specified volume of simulant.

Where the surface to volume ratio to be used in contact with food is not known conventional conditions should be used, as described in the following subclauses of this clause.

6.3 Single surface versus double surface testing (by total immersion)

The Commission Directive (90/128/EEC) (C.1) requires that the test should be performed in such a way that only those parts of the sample intended to come into contact with foodstuffs in actual use will be in contact with the foodstuff or simulant. However, it should be permissible to demonstrate compliance with migration limits by the use of a more severe test.

In the total immersion test both the surface which is intended to come into contact with the foodstuff and the outside surface are in contact with the food simulant. No allowance is made for this in the calculation of migration per unit of surface area. Although the total surface exposed is 2 dm^2, only 1 dm^2 (i.e. the food contact surface, is taken into account in the calculation. It is therefore a more severe test than testing in a pouch or in a cell or by filling.

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However, for symmetrical samples only, it may be possible to demonstrate that including both surfaces in the calculation may be valid. This is when it has been shown that the value for overall migration obtained in the total immersion test including both surfaces in the calculation is, allowing for analytical tolerance, the same as that obtained by single surface testing.

SIST ENV 1186-1:1997
https://standards.iteh.ai/catalog/standards/sist/...
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Samples of test specimens with cut edges tend to give higher results than those without. In use the plastics article would not normally have cut edges in contact with the foodstuff. Therefore, in calculating the overall migration result as milligrams of the constituents released per square decimetre, the area of the cut edges should not be taken into account.

Testing samples with the test specimens prepared by cutting sections from the plastic and totally immersing in the food simulant, is a more severe test.

The surface to volume ratio in the total immersion test is conventionally 1 dm^2 of food contact area to 100 ml of food simulant.

The method for determining overall migration by total immersion with olive oil is given in ENV 1186-2 and with aqueous food simulants in ENV 1186-3.

6.4 Single surface testing using a standard cell

Where single surface testing is the preferred procedure, particularly important for multi-layer articles, this may be carried out in a standard cell or in an equivalent cell. For samples that may be obtained in flat form,