

English version

Materials and articles in contact with foodstuffs — Polymeric coatings on paper and board — Guide to the selection of conditions and test methods for overall migration

Matériaux et objets en contact avec les denrées alimentaires – Revêtements polymères sur papier et carton
– Guide pour le choix des conditions et des méthodes d'essai en matière de migration globale

Werkstoffe und Gegenstände in Kontakt mit Lebensmitteln
- Polymere Beschichtungen auf Papier und Pappe –
Leitfaden für die Auswahl von Prüfbedingungen und
Prüfverfahren für die Gesamtmigration

This Technical Specification (CEN/TS) was approved by CEN on 28 July 2002 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

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Foreword

This document (CEN/TS 14234:2002) has been prepared by Technical Committee CEN/TC 194, "Utensils in contact with food", the secretariat of which is held by BSI.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this document.

In this standard the Annex A is normative and Annex B is informative.

Guidance for migration testing of polymeric coatings on cellulosic substrates (paper and board) is given in the informative annex B.

At the time of preparation and publication of this Technical Specification the European Union legislation relating to resinous and polymeric coatings on paper and board has not been formulated.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Specification: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

1 Scope

This Technical Specification specifies test methods for 'alternative tests' and 'substitute tests' performed with volatile test media, iso-octane and a volume fraction of 95 % aqueous ethanol, for the determination of overall migration from polymeric coatings on paper and board intended to come into contact with fatty foodstuffs.

NOTE 1 It also includes guidance for the application of Council Directive 82/711/EEC [1], as last amended by Commission Directives 93/8/EC and 97/48/EC [2] [3] as regards the determination of the specific and overall migration into fatty food simulants (fat test) and includes a glossary to clarify the terminology used, see annex B.

NOTE 2 The iso-octane and a volume fraction of 95 % aqueous ethanol volatile test media used in these test methods are those specified for 'substitute tests' in Council Directive 82/711/EEC and its subsequent amendments. In addition to the use of iso-octane and 95 % v/v aqueous ethanol as test media for 'substitute tests', Council Directive 82/711/EEC and its subsequent amendments specifies the use of modified polyphenylene oxide as a test medium for use at temperatures of 100 °C and above. A test method for overall migration from polymeric coatings intended to come into contact with fatty foodstuffs using modified polyphenylene oxide (MPPO) is in preparation.

NOTE 3 These test methods can also be used for the 'alternative tests' described in Council Directive 82/711/EEC and its subsequent amendments, when the chosen volatile test media are iso-octane and a volume fraction of 95 % aqueous ethanol, see ENV 1186-1.

A suggested test scheme is given in Figure A.1. If the test result obtained by the total immersion method, described in clause 4 of this Technical Specification, exceeds the allowed overall migration limit the single-sided migration test using a cell, see clause 5, if technically feasible; may be used. If it is not possible to use the single sided cell method, e.g. because of pinholes, use adsorption by modified polyphenylene oxide, (MPPO).

Iso-octane is used as a test medium for test samples coated with non polar food contact layers, such as polyolefins. For test samples coated with polar food contact polymers such as polyamide and polyethylene terephthalate, a volume fraction of 95 % aqueous ethanol is used. For polystyrenes, plasticised polyvinyl chloride and other polymers where the identification or polarity of the polymer is not clear, two parallel tests shall be conducted using both of the proposed test media and taking the higher value obtained as the relevant result.

NOTE 4 The nature of the food contact layer determines the selection of the test medium(a).

NOTE 5 The overall migration limit for materials and articles of an all polymeric construction is specified in Commission Directive 90/128/EEC [4] and the conditions of test in Council Directive 82/711/EEC [1] and its subsequent amendments, [2],[3]. There is an expectation that the scope of this directive will be extended to cover polymeric coatings on paper and board.

The 'substitute tests' described in this Technical Specification are by total immersion, see clause 4 and in a migration cell, see clause 5.

NOTE 6 The test conditions are those described in Council Directive 82/711/EEC [1] and its subsequent amendments, [2],[3].

The 'alternative test' methods described here specifies a rapid extraction test with a 'more severe' test character, for the assessment of the overall migration into fatty food simulants. The method differs from the substitute test methods only in the combination of test time and test temperature. The method is based on the determination of the extraction of migrateable substances from polymeric coated paper or board, which are intended to come into contact with foodstuffs, by total immersion in non-polar, iso-octane, and/or polar, ethanol, solvents depending on the polarity of the polymeric coating. According to the results obtained by this method, see [5],[6],[7],[8],[9] and taking physio-chemical considerations into account, the obtained extraction efficiency has, generally, been found to be equivalent to or higher than overall migration results obtained using fat simulant D, under the test conditions, 10 days at 40 °C, 2 h at 70 °C, 1 h at 100 °C, 30 min at 121 °C and 30 min at 130 °C.

NOTE 7 This method is not applicable to test materials intended for applications over 130 °C. Test materials intended for applications over 70 °C have to be checked for their physical suitability at the intended time and temperature of use.

The test method should be applied to polymer coated packagings where the polymer layer is less than 300 µm in thickness. However, if this extraction test is applied to materials with coatings with higher thickness than 300 µm and the result does not exceed any allowed overall migration limit then the method is considered to be suitable for those materials.

In those cases where the rapid extraction test by total immersion, yields total extraction values that exceed the overall migration limit or may be technically unsuitable a cell test method using the same time and temperature conditions is applicable. This cell test method should primarily only be applied to packagings with a physical barrier layer (for instance of aluminium or other material to prevent penetrative loss of test medium) and which have a thinner food contact layer than 300 µm. This test method can not be applied if the polymeric coating is shown to have pinholes.

2 Normative references

This Technical Specification 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 Technical Specification only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

ENV 1186-1:1994	Materials and articles in contact with foodstuffs – Plastics - Guide to the selection of conditions and test methods for overall migration
ISO 648	Laboratory glassware – One-mark pipettes
ISO 4788	Laboratory glassware - Graduated measuring cylinders

3 Test conditions

3.1 'Substitute test' methods

For substitute tests, the conditions of test will be determined by the conditions of use, see clauses 4, 5 and 6 of ENV 1186-1:1994.

3.2 'Alternative test' methods

For alternative tests, the test medium (a) and test conditions are to be selected according to the nature of the polymeric coating as given by Table 1.