SLOVENSKI STANDARD
SIST-TS CEN/TS 16677:2014

01-julij-2014

Očesna optika - Referenčna preskusna metoda za ugotavljanje sproščanja niklja iz okvirjev očal in sončnih očal

Ophthalmic optics - Reference method for the testing of spectacle frames and sunglasses for nickel release

Augenoptik - Referenzprüfverfahren zur Bestimmung der Nickellässigkeit von Brillenfassungen und Sonnenbrillen

Optique ophtalmique - Méthode d'essai de référence relative à la libération du nickel par les montures de lunettes et les lunettes de soleil

Ta slovenski standard je istoveten z: **CEN/TS 16677:2014**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST-TS CEN/TS 16677:2014 **en,fr,de**

TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

CEN/TS 16677

May 2014

ICS 11.040.70

English Version

Ophthalmic optics - Reference method for the testing of spectacle frames and sunglasses for nickel release

Optique ophtalmique - Méthode d'essai de référence relative à la libération du nickel par les montures de lunettes et les lunettes de soleil

Augenoptik - Referenzverfahren für die Bestimmung der Nickellässigkeit von Brillenfassungen und Sonnenbrillen

This Technical Specification (CEN/TS) was approved by CEN on 15 March 2014 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.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. CEN/TS 16677:2014 E

Contents

Page

Foreword 4

Introduction 5

1 Scope 6

2 Normative references 6

3 Terms and definitions 6

4 Principle 7

5 Sampling and preparation of test samples 8
5.1 Selection of test samples 8
5.2 Preparation and conditioning of test samples 8

6 Simulation of wear and corrosion 9

7 Coating test 9
7.1 General 9
7.2 Apparatus and consumables 9
7.3 Preparation of test samples for coating test 10
7.3.1 Parts to be tested 10
7.3.2 Dismantling and/or cutting and/or masking 11
7.3.3 Determination of test area 12
7.3.4 Preparation of electrical contact area 12
7.4 Preparation of saline solution 13
7.5 Procedure 13
7.5.1 Preparation of the electro-chemical cell 13
7.5.2 Insertion and connection of the test part in the electro-chemical cell 13
7.5.3 Determination of open circuit potential and measurement of electrochemical impedance of samples 14
7.5.4 Calibration of the potentiostat 14
7.6 Calculation of results 14
7.7 Test report 15

8 Release of nickel and its quantitative analytical detection (migration test) 15
8.1 General 15
8.2 Apparatus and consumables 16
8.3 Preparation of test samples for migration test 17
8.3.1 Parts to be tested 17
8.3.2 Guidance on selection of test areas on the parts to be tested 18
8.3.3 Dismantling and degreasing 18
8.4 Procedure 18
8.4.1 Preparation of test paper including determination of its area 18
8.4.2 Preparation of artificial sweat solution 19
8.4.3 Applying artificial sweat to the test paper and attaching it to the test sample 21
8.4.4 Incubation of test sample with test paper attached (release of nickel into paper) 21
8.4.5 Retrieval of the test paper from the test samples 22
8.4.6 Analysis of the paper for nickel present 22
8.5 Calculation of results 24
8.6 Interpretation of results 25
8.6.1 General 25
8.6.2 Assessment of non-compliance 25

8.7 Test report 25
Annex A (informative) Cutting and masking of test samples (Coating test) 27
A.1 Fronts 27
A.2 Sides (temples) 28
Annex B (normative) Selection of test areas and wrapping (Migration test) 29
B.1 Rims 29
B.2 Bridge and brace bar 30
B.3 Sides (temples) 31
B.4 Wrapping with sealing film 32
Bibliography 33

Foreword

This document (CEN/TS 16677:2014) has been prepared by Technical Committee CEN/TC 170 “Ophthalmic optics”, the secretariat of which is held by DIN.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Specification: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

This document has been prepared under Mandate M/448 issued by the European Commission in the framework of Regulation (EC) No 1907/2006, REACH, in particular Commission Regulation (EC) No 552/2009 of 22 June 2009 amending regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and restriction of Chemicals (REACH) as regards Annex XVII RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES.

The aim of the mandate is the revision of the method of analysis to detect the release of nickel from spectacle frames and sunglasses.

The availability of the new reference method for the determination of the release of nickel from spectacle frames and sunglasses will provide the reliable framework to enforce the limit value for nickel release of 0,5 µg/cm^2/week set forth by European Regulation. It will ensure a uniform application and control of the European legislation in all member states.

Harmonising the test method for nickel release in all member states is vital with a view to protecting effectively the health of the end consumer, that is, the spectacle wearer. Nickel allergy is still the most frequent contact allergy in Europe and a significant health issue.

1 Scope

This document specifies the reference method for the testing of spectacle frames, ready-to-wear spectacles, sunglasses and other items for eye and face protection for nickel release.

The reference method supports the demonstration of conformity with the limit value for nickel release of 0,5 µg/cm^2/week set forth by European Regulation.

The reference method involves the procedural steps shown in Figure 1 and described in Clause 4.

This document applies to those parts of metal spectacle frames and those metal parts of combination spectacle frames that are intended to come into direct and prolonged contact with the skin of the wearer. This document also applies to those relevant metal parts of ready-to-wear spectacles, sunglasses and other items for eye and face protection.

NOTE The reference method for articles apart from spectacle frames, ready-to-wear spectacles, sunglasses and other items for eye and face protection is specified in EN 1811.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 12472, *Method for the simulation of wear and corrosion for the detection of nickel release from coated items*

EN ISO 3696:1995, *Water for analytical laboratory use - Specification and test methods (ISO 3696:1987)*

EN ISO 11380, *Optics and optical instruments - Ophthalmic optics - Formers (ISO 11380)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
article
spectacle frame, ready-to-wear spectacles, sunglass or other item used for eye and face protection to which the scope of this document applies

3.2
test sample
spectacle frame, ready-to-wear spectacle, sunglass or other item used for eye and face protection submitted for testing

Note 1 to entry: Fronts or sides may be submitted separately for testing.

3.3
test part
that part of a test sample that is intended to come into direct and prolonged contact with the skin and shall be tested

Note 1 to entry: These parts are defined in 7.3.1 (for the coating test) and in 8.3.1 (for the migration test).

3.4
test paper
piece of paper used for testing, at any stage of the procedure

3.5
extraction solution
solution obtained after extracting the test paper

3.6
appropriate tool
tool enabling the procedure to be performed without causing contamination by nickel or other metal ions, either from the material of the tool or deposits on it

Note 1 to entry: Such tools could be made from plastics, titanium, or stainless steels.

3.7
appropriate equipment
equipment enabling the procedure to be performed without causing contamination by nickel or other metal ions, either from the material of the equipment or deposits on it

4 Principle

Following the simulation of wear and corrosion for coated test parts, according to the method specified in EN 12472, the reference method comprises the following procedural steps:

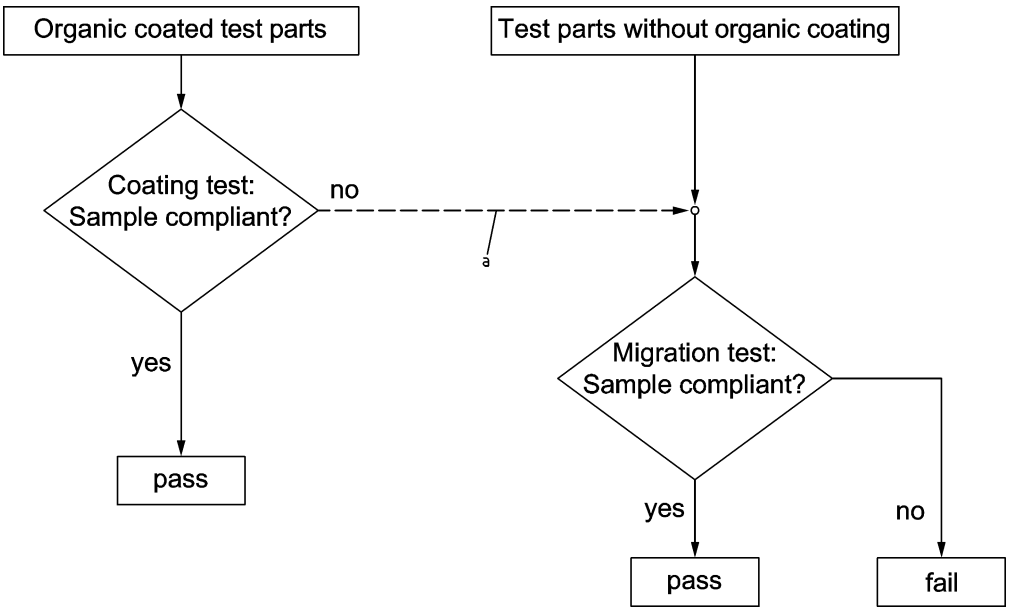
1) Coating test, applicable only to test parts with an organic coating, based on Electrochemical Impedance Spectroscopy (EIS) and specified in Clause 7; the coating test aims at demonstrating that the coating of the test sample is of sufficient quality to prevent the release of nickel, thereby ensuring that the test sample's nickel release does not exceed the regulatory limit. The coating test is, however, sensitive to all ions, so an article may pass the migration test even though it failed the coating test.

2) Migration test for nickel ion release, specified in Clause 8; the migration test makes provision for quantitative testing for the amount of nickel released, to determine whether or not the article's nickel release exceeds the regulatory limit. The migration test comprises two steps: Release of nickel by artificial sweat into a test paper and the subsequent quantitative analytical detection of the nickel released into the paper.

For an article that failed the coating test, either new test samples or, subject to the requirements of the person ordering the test, the original test samples may be subjected to the migration test.

Figure 1 illustrates the procedure.

Requirements for sampling and guidance as to which parts of the articles shall be subject to testing (the test parts) are given in 5.1, and in 7.3.1 (for the coating test) and 8.3.1 (for the migration test).



[a] The coating test is sensitive to all ions, so an article may pass the migration test even though it failed the coating test.

Figure 1 — Flowchart

5 Sampling and preparation of test samples

5.1 Selection of test samples

Two specimens of each article to be tested shall be selected at random for either the coating or the migration test.

The selected specimens shall be identified as test sample 1 and test sample 2.

Subject to the agreement by the person ordering the test, test samples used for the coating test can be tested in a subsequent migration test, but not vice versa.

If a test sample is likely to be subjected to the migration test after the coating test, it shall be washed in deionised water immediately after the coating test and allowed to dry to avoid corrosion from sodium chloride. It is preferable that new test samples are used for the migration test.

Prior to performing the coating test (see Clause 7) and the migration test (see Clause 8), as applicable, all test samples shall be prepared and conditioned as specified in 5.2, then be subjected to the simulation of wear and corrosion as specified in EN 12472 (see Clause 6).

5.2 Preparation and conditioning of test samples

For spectacle frames, if not already fitted with dummy or demonstration lenses, the test samples shall be fitted with a pair of suitable organic lenses within the range of -1,00 D to +1,00 D and with an edge thickness of between 1,5 mm and 2,5 mm. These test lenses shall be edged either in accordance with the manufacturer's electronic instructions or with a digitally controlled edging machine that uses the tracing made of the individual test sample or, where appropriate, using a mechanical former in accordance with EN ISO 11380. The bevel angle of the edged lens shall be 120° -2° +3° for spectacle frames featuring a rim with a groove.

Sides and fronts shall be separated from each other, and end covers (side tips) removed from sides where appropriate. Unless they have a metal-bearing surface, remove nose pads before the wear phase.

Dismantling of sides from fronts may be done either by unscrewing the joint screw or by cutting the joint across the charniers.

WARNING: Care shall be taken not to damage the coating on the frame on areas that are subsequently tested, particularly the coating near the cut.

Ensure that all the separate test parts remain identified throughout all steps of the overall procedure.

6 Simulation of wear and corrosion

Prior to submission to the selected test, the test samples shall be subject to the method for simulation of wear and corrosion according to EN 12472.

Fix fronts and sides separately onto the retaining system and slide into the rotating barrel.

When the accelerated wear and corrosion process is completed, remove the test samples. Gently swirl the sample(s) for 2 min in degreasing solution at room temperature. Rinse thoroughly with de-ionised water. Gently dry in a clean air stream or allow to dry on absorbent paper. After degreasing, handle the samples with appropriate tools or clean laboratory gloves.

Remove lenses from fronts by unscrewing the closing block joint.

NOTE Pushing dummy lenses out is very likely to damage the coating, while the alternative test lenses specified in EN ISO 12870 can be removed only by unscrewing.

Disassemble three-piece rimless fronts. Disassemble fronts of combination frames and remove any plastics parts.

Then subject the test parts to the selected test: Coating test, see Clause 7, and/or migration test, see Clause 8.

7 Coating test

7.1 General

The purpose of the coating test is to verify if the surface treatment of an article is able to limit the release of metal ions (hence including nickel), in order to identify good quality coatings. Test samples that are not identified as "pass" may be subjected to the migration test, see Clauses 4 and 5.

The parts of spectacle frames needing consideration are only those intended to come into direct and prolonged contact with the skin of the wearer, see 7.3.1.

7.2 Apparatus and consumables

7.2.1 Masking agent, suitable for electroplating purposes and capable of electrically insulating the test part from the saline solution. Application of more than one coat is acceptable, and may be preferable.

Test the masking agent to verify that it is suitable by using it to coat a metal rod without an organic coating and show that the adhesion is good and impedance results are high (greater than 50 MΩ).

It is recommended that the masking agent be coloured or fluorescent, to make the masked areas more visible.

NOTE Lacomit is the trade name of a suitable product.[1)]

7.2.2 Deionised water, according to EN ISO 3696:1995, grade 3 or to Ph.Eur., for rinsing and preparation of the saline solution (7.4).

7.2.3 Sodium chloride of recognised pro analysis, p.a., grade or better, for preparation of the saline solution (7.4);

7.2.4 Degreasing solution, Sodium Dodecyl Sulphate (SDS) at a concentration of 2 % in deionised water, to clean the test samples after cutting, etc. and before testing. An appropriately diluted, neutral, commercially available detergent may also be used.

7.2.5 Apparatus for preparation of 1 % saline solution in deionised water.

7.2.6 Electro-chemical cell, made of glass, suitable for mounting firstly a Standard Calomel (SCE) or Ag/AgCl Reference Electrode, secondly a Graphite or Platinum Counter Electrode and thirdly, the test part.

NOTE The recommended counter electrode is a high density pure graphite rod, approximately 6 mm in diameter.

7.2.7 Laboratory clamps, suitable for holding the (cut) test sample, as required to immerse the selected area in electrolyte in the electro-chemical cell, but keeping the electrical contact area dry.

7.2.8 Potentiostat, having the ability to perform A.C. Electrochemical Impedance Spectroscopy (EIS) at 1 Hz and having a current sensitivity of better than 1 pA.

NOTE An example of suitable apparatus is Gamry apparatus series 600 with EIS 300 software package.[2)]

7.2.9 Electrical clamps, e.g. small crocodile clips, capable of providing secure electrical contact with the test sample, reference and counter electrodes.

7.2.10 Calibration (dummy) cell, usually supplied by the potentiostat manufacturer together with the instrument, appropriate to test the potentiostat in the impedance range expected.

7.2.11 Appropriate tools, needed to perform the procedure. See 3.6 for the definition of "appropriate" tools. To prevent possible contamination by nickel or other metal ions, clean all tools well before use.

7.2.12 Laboratory gloves, e.g. latex or PVC, but not cotton.

7.2.13 Faraday cage; either an earthed Faraday cage, aluminium foil or conductive cloth to house the electro-chemical cell during measurement.

7.3 Preparation of test samples for coating test

7.3.1 Parts to be tested

See subclause 5.1 for sampling requirements.

For testing of articles with the coating test, the parts to be tested are:

---

1) Lacomit is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by CEN of this product. Equivalent products may be used if they can be shown to lead to the same results.

2) Gamry apparatus series 600 with EIS 300 software package is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by CEN of this product.