SLOVENSKI STANDARD
SIST EN 16128:2011

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Nadomešča:
SIST EN 1811:1999+A1:2008

Primerjalna preskusna metoda za sproščanje niklja iz tistih delov okvirjev očal in sončnih očal, ki so predvideni za neposredni in daljši stik s kožo

Reference test method for release of nickel from those parts of spectacle frames and sunglasses intended to come into close and prolonged contact with the skin

Referenzprüfverfahren zur Bestimmung der Nickellässigkeit derjenigen Teile von Brillenfassungen und Sonnenbrillen, die bestimmungsgemäß unmittelbar und länger mit der Haut in Berührung kommen

Méthode d'essai de référence relative à la libération du nickel par les parties des montures de lunettes et lunettes de soleil destinées à entrer en contact direct et prolongé avec la peau

Ta slovenski standard je istoveten z: **EN 16128:2011**

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11.040.70	Oftalmološka oprema	Ophthalmic equipment

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EUROPEAN STANDARD

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English Version

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This European Standard was approved by CEN on 9 January 2011.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (EN 16128:2011) has been prepared by Technical Committee CEN/TC 170 “Ophthalmic optics”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2011, and conflicting national standards shall be withdrawn at the latest by September 2011.

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.

This document, together with EN 1811:2011, supersedes EN 1811:1998+A1:2008.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

This document supports essential requirements of Commission Regulation (EC) No 1907/2006 (REACH) of the European Parliament and the Council.

List of the significant technical changes that have been made in this new version of EN 1811 in comparison with the former edition EN 1811:1998+A1:2008:

The scope of the former European Standard was divided: EN 1811:2011 is applicable for all products but spectacle frames and sunglasses; EN 16128:2011 is applicable for spectacle frames and sunglasses;

List of the significant technical changes of EN 1811:2011 as compared to the former European Standard:

- The scope was expanded to include all post assemblies which are inserted into pierced parts of the human body;
- The preparation of the test solution was tested and changed;
- The correction factor was eliminated and the concept of measurement uncertainty introduced;
- The Standard contains a new normative Annex C on the preparation of articles prior to nickel testing;

EN 16128:2011 is technically unchanged as compared to the former European Standard EN 1811:1998+A1:2008.

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

Introduction

Adverse skin reaction to nickel has been known for many decades. Nickel is now the most frequent cause of contact allergy in Europe, and 10 % to 20 % of the female population is allergic to nickel. Skin absorption of nickel ions, which are released from some nickel-containing materials in direct and prolonged contact with the skin, causes sensitisation. Further exposure to soluble nickel salts results in allergic contact dermatitis. It is known that sensitisation to nickel requires higher exposure levels than does the elicitation in already sensitised individuals. There is a large variation in the degree of sensitivity to nickel between individuals. This widespread health problem has forced the urgent introduction of a number of measures designed to reduce its prevalence. They include this standard which attempts to provide an *in-vitro* chemical test that correlates as far as possible with the variable human biological reactions that occur when metallic articles containing nickel are in direct and prolonged contact with the skin. The standard provides a measure of the amount of nickel release from an article immersed for one week in artificial sweat. It is a first attempt at the standardisation of a test method that previously has been used in research, and it is expected to require early revision in the light of further experience. The standard also describes the preparation of a reference material intended to assist a laboratory in achieving an acceptable precision.

Clinical patch-testing of a small selection of nickel-containing alloys and coatings on nickel-sensitized persons indicates that high and low results achieved with the present analytical method correspond closely with patch-test reactivity. Moreover, a nickel release rate threshold of 0,5 $\mu g/cm^2$/week has been set in European Parliament and Council Directive 94/27/EC (OJ No. L188 of 22.7.94). In order to ensure that articles yielding values near this figure are not unnecessarily excluded from European trade as a result of the difficulties inherent in the test method, particularly when applied to intricately-shaped articles, the measured release figures are multiplied by a factor of 0,1. Materials recognized as causing sensitisation to nickel would not become acceptable by use of this adjustment. Application of this standard is confidently expected to reduce significantly the development of allergic contact dermatitis due to nickel. Experience of its use and further epidemiological and clinical research may justify changes to test procedure and/or interpretation of the test result.

1 Scope

This European Standard specifies a method for simulating the release of nickel from those parts of spectacle frames and sunglasses intended to come into direct and prolonged contact with the skin in order to determine whether they release nickel at a rate greater than 0,5 µg/cm^2/week.

NOTE 1 This European Standard, EN 16128, has been prepared in reply to the European Commission's Mandate M/448 addressed to CEN. From the technical point of view, this European Standard provides an unchanged re-publication of the technical requirements that had previously been specified in EN 1811:1998, but restricted in scope to apply only to spectacle frames and sunglasses.

NOTE 2 Users of this European Standard may wish to note that, also in reply to the European Commission's Mandate M/448, this European Standard is currently subject to review with the objective of developing a new standardized method to supersede this European Standard when the new method becomes available.

NOTE 3 Nickel release testing of products other than spectacle frames and sunglasses is specified in EN 1811:2011.

2 Principle

The parts to be tested for nickel release are placed in an artificial sweat test solution for 1 week. The concentration of dissolved nickel in the solution is determined by atomic absorption spectrometry, inductively-coupled plasma spectrometry or other appropriate analytical method. The nickel release is expressed in micrograms per square centimetre per week (µg/cm^2/week).

3 Reagents

Except where indicated, all reagents shall be of recognized pro analysis, p.a., grade or better and shall be free of nickel.

3.1 Deionized and aerated water.

Fill a tall-form 2-l beaker with deionized water, specific conductivity max. 1 µS/cm. Saturate with air by attaching a gas distribution tube (porosity 1) to a cork and positioning the lower end of the tube on the bottom of the beaker. Allow grease-free air to flow at a rate of 150 ml/min. for 30 min.

3.2 Sodium chloride.

3.3 DL-Lactic acid, ρ = 1,21 g/ml, >88 % (*m/m*)**.**

3.4 Urea.

3.5 Ammonia solution, ρ = 0,91 g/ml, 25 % (*m/m*).

3.6 Dilute ammonia solution, 1 % (*m/m*).

Transfer 10 ml of ammonia solution (3.5) into a 250-ml beaker containing 100 ml of deionized water. Stir and cool to room temperature. Transfer the solution to a 250-ml volumetric flask and make up to volume with deionized water.

3.7 Nitric acid, ρ = 1,40 g/ml, 65 % (*m/m*).

3.8 Dilute nitric acid, approximately 5 % (*m/m*).

Transfer 30 ml of nitric acid (3.7) into a 500-ml beaker containing 350 ml of deionized water. Stir and cool to room temperature. Transfer the solution to a 500-ml volumetric flask and make up to volume with deionized water.

3.9 Degreasing solution.

Dissolve 5 g of an anionic surface-active agent such as sodium dodecylbenzene sulfonate or sodium alkylaryl sulfonate in 1 000 ml water. An appropriately-diluted, neutral, commercially-available detergent may be used.

3.10 Wax or lacquer (suitable for electroplating purposes) capable of protecting a surface from nickel release.

The wax or lacquer shall be shown to prevent nickel release from a nickel-releasing surface when one or more coats of the wax or lacquer are applied in the same manner as on a test sample, and tested for nickel release according to Clause 6 (see Annex C).

4 Apparatus

4.1 A pH-meter, accurate to ± 0,02 pH.

4.2 An analytical spectrometer capable of detecting a concentration of 0,01 mg nickel per litre. The instrument shall, after optimization, meet the performance criteria given in 4.2.1 and 4.2.2. It is recommended that either an inductively-coupled plasma – optical emission spectrometer or an electrothermal excitation atomic absorption spectrometer is used.

4.2.1 Minimum precision.

The standard deviation of 10 measurements of the absorption of a full matrix calibration solution containing 0,05 mg nickel per litre shall not exceed 10 %.

4.2.2 Limit of detection.

The limit of detection shall be considered as twice the standard deviation of 10 measurements of the absorbance of a full matrix solution containing nickel at a concentration level selected to give an absorbance just above that of the zero calibration solution. The limit of detection of nickel in a matrix similar to the final test solution shall be better than 0,01 mg/l.

4.3 Thermostatically controlled water-bath or oven, capable of maintaining a temperature of (30 ± 2) °C.

4.4 A vessel with lid, both composed of a non-metallic, nickel-free and nitric-acid-resistant material, such as glass and/or polypropylene and/or polytetrafluoroethylene and/or polystyrene. The sample shall be suspended in the liquid by a holder made from the same materials as listed above, so as to minimize contact of the sample area (5.1.1) with the walls and base of the vessel. The size and shape of vessel and holder shall be chosen so as to minimize the volume of test solution required to completely cover the object to be tested.

In order to remove any trace of nickel, the vessel and holder shall be pre-treated by being stored in a solution of dilute nitric acid (3.8) for at least 4 h. After acid treatment, rinse the vessel and holder with deionized water and dry.

5 Samples

5.1 Sample area

5.1.1 Definition of sample area

Only the surface(s) of those parts of spectacle frames or sunglasses (referred to hereafter as "frames") liable to come into direct and prolonged contact with the skin [1)] shall be analyzed. In this standard such surfaces are defined as "sample area".

5.1.2 Determination of sample area

Determination of the sample area (a) in square centimetres is achieved by marking the contour of the sample area defined in 5.1.1 (see Annex C). In order to achieve the required degree of analytical sensitivity, a minimum sample area of 0,2 cm^2 shall be tested. If necessary, identical items may be treated together to obtain this minimum area.

NOTE If a frame is being tested to ascertain its conformity with Directive 94/27/EC, the accuracy with which the sample area of the frame or part has to be determined is dependent on the nickel release of the frame or part. The closer the nickel release is to 0,5 $\mu g/cm^2$/week, the limit laid down in the directive, the more accurately the surface area has to be determined.

5.1.3 Areas other than sample areas

In order to prevent release of nickel from areas other than the sample area, such areas shall be removed or protected from the test solution. This may be achieved after degreasing (see 5.2) by, for example, the application of one or more coatings of a wax or lacquer which has been shown to protect from nickel release (3.10). Annex C gives guidance on the coating of protected areas prior to testing. Where it is not feasible to remove or protect all areas other than the sample area, for example with certain watch bracelets, such unprotected surfaces shall be considered as part of the sample area.

NOTE If, when non-significant surfaces are considered to be part of the sample area, the nickel release from the frame is found to be unacceptable, consideration should be given to dismantling the frame and testing any internal components for nickel release. If the nickel release from such internal components is significant it might be appropriate to test the external components on their own, assuming that they are available, or the materials from which the frame has been manufactured (see Annex D).

5.2 Sample preparation

Gently swirl the sample for 2 min in degreasing solution (3.9) at room temperature. Rinse thoroughly with deionized water and dry. After degreasing, items should be handled with plastic forceps or clean protective gloves.

NOTE This cleaning stage is intended to remove extraneous grease and skin secretions due to handling, but not any protective coatings. However, it will also substantially remove any nickel contamination that might be present on the surface of the sample. If there is a requirement to determine this nickel the cleaning stage should be omitted. However, it should be appreciated that omission of this cleaning stage might itself affect the nickel release from the sample.

5.3 Reference disc

As a quality control check, the nickel release from a reference disc may be determined (see Annex A and Annex B).

If used, it is important that both sides of a reference disc are abraded before each test. A minimum of 0,05 mm shall be abraded from each surface using wet emery paper No. 600 followed by No. 1200. The disc is then degreased in the same way as the sample (5.2).

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1) See EN ISO 12870 for guidance.