SLOVENSKI STANDARD
kSIST FprEN 16128:2010

01-september-2010

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: **FprEN 16128**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

kSIST FprEN 16128:2010 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
FprEN 16128

July 2010

ICS

Will supersede EN 1811:1998+A1:2008

English Version

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If this draft becomes a European Standard, 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.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (FprEN 16128:2010) has been prepared by Technical Committee CEN/TC 170 “Ophthalmic optics”, the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

This document, together with prEN 1811:2009, 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, and supports essential requirements of Commission Regulation (EC) No 1907/2006 (REACH) of the European Parliament and the council.

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 µg/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, FprEN 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 prEN 1811:2009.

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 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 1000 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.