



BSI Standards Publication

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

National foreword

This British Standard is the UK implementation of EN 16128:2011. Together with BS EN 1811:2011, it supersedes BS EN 1811:1998+A1:2008, which will be withdrawn on 1 March 2013.

NOTE: BSI, as the UK member body of CEN, has adopted EN 1811:2011 as a British Standard. However, the content of EN 1811:2011 was voted against by UK committee STI/53, Specifications and test methods for jewellery and horology, during its development.

The UK participation in its preparation was entrusted to Technical Committee CH/172/3, Spectacles.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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EN 16128

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Supersedes EN 1811:1998+A1:2008

English Version

**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**

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

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

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.

CEN members are the national standards bodies of 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 United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
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Management Centre: Avenue Marnix 17, B-1000 Brussels

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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 $0,5 \mu\text{g}/\text{cm}^2/\text{week}$ 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 $0,5 \mu\text{g}/\text{cm}^2/\text{week}$.

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 ($\mu\text{g}/\text{cm}^2/\text{week}$).

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. $1 \mu\text{S}/\text{cm}$. 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, $\rho = 1,21 \text{ g/ml}$, $>88 \%$ (m/m).

3.4 Urea.

3.5 Ammonia solution, $\rho = 0,91 \text{ g/ml}$, 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, $\rho = 1,40 \text{ g/ml}$, 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.