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Irish Standard Recommendation
S.R. CEN/TS 16677:2014

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

S.R. CEN/TS 16677:2014

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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

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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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CEN/TS 16677:2014 (E)

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/cm²/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.

CEN/TS 16677:2014 (E)**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 $0,5 \mu\text{g}/\text{cm}^2/\text{week}$ 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

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