SLOVENSKI STANDARD
SIST EN 1811:2011/kFprA1:2015

01-maj-2015

Primerjalna preskusna metoda za sproščanje niklja iz izdelkov, vstavljenih v prebodene dele človeškega telesa, in izdelkov, ki so v neposrednem in daljšem stiku s kožo

Reference test method for release of nickel from all post assemblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin

Referenzprüfverfahren zur Bestimmung der Nickellässigkeit von sämtlichen Stäben, die in durchstochene Körperteile eingeführt werden und Erzeugnissen, die unmittelbar und länger mit der Haut in Berührung kommen

Méthode d'essai de référence relative à la libération du nickel par les assemblages de tiges qui sont introduites dans les parties percées du corps humain et les produits destinés à entrer en contact direct et prolongé avec la peau

Ta slovenski standard je istoveten z: **EN 1811:2011/FprA1:2015**

ICS:

39.060	Nakit	Jewellery

SIST EN 1811:2011/kFprA1:2015 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
EN 1811:2011

FprA1

February 2015

ICS 39.060

English Version

Reference test method for release of nickel from all post assemblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin

Méthode d'essai de référence relative à la libération du nickel par les assemblages de tiges qui sont introduites dans les parties percées du corps humain et les produits destinés à entrer en contact direct et prolongé avec la peau

Referenzprüfverfahren zur Bestimmung der Nickellässigkeit von sämtlichen Stäben, die in durchstochene Körperteile eingeführt werden und Erzeugnissen, die unmittelbar und länger mit der Haut in Berührung kommen

This draft amendment is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 347.

This draft amendment A1, if approved, will modify the European Standard EN 1811:2011. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

This draft amendment was established by CEN 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, 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.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

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

Foreword

This document (EN 1811:2011/FprA1:2015) has been prepared by Technical Committee CEN/TC 347 “Methods for analysis of allergens”, the secretariat of which is held by SNV.

This document is currently submitted to the Unique Acceptance Procedure.

1 Modifications to 9.2, Interpretation of results

Replace the header of 9.2.2 with "9.2.2 Conformity assessment"

Delete the existing text in 9.2.2.2 and replace it with the following:

"Because of the combined measurement uncertainty of 46 %, an article is non-compliant only when the nickel release is greater than or equal to 0,88 µg/cm^2/week. Hence an article shall be accepted and be permitted to be placed on the market if the measured value is less than 0,88 µg/cm^2/week.

NOTE For further explanation, see Annex A."

Delete the existing text in 9.2.2.3 and replace it with the following:

"Because of the combined measurement uncertainty of 46 %, an article is non-compliant only when the nickel release is greater than or equal to 0,35 µg/cm^2/week. Hence an article shall be accepted and be permitted to be placed on the market if the measured value is less than 0,35 µg/cm^2/week.

NOTE For further explanation, see Annex A."

2 Modification to Annex A

Replace Annex A with the following:

"

Annex A
(informative)

Expanded measurement uncertainty of the test procedure and compliance assessment

The results of an inter-laboratory comparison undertaken in 2008 according to ISO 5725 gave as an estimate for the combined expanded measurement uncertainty a value of $u_{t,r}$ = 46 %. The performance characteristic $u_{t,r}$ is related to the relative reproducibilities of the surface area determination and the analytical determination of the nickel release by the following formula:

$$u_{t,r}^2 = s_{R,r}^2(area) + s_{R,r}^2(Ni) \quad \text{(A.1)}$$

In order to determine whether a tested article is non-compliant with its respective limit, a t-test is applied. This test decides whether a determined nickel release value significantly exceeds its limit. This is the case when the lower confidence interval boundary of the measured release exceeds the legally prescribed limit. This may be re-formulated in a way that a value significantly exceeds the limit if it is larger than the limit plus one half of the width of the confidence interval of the measured value. The confidence interval of the measured value is assessed as the expanded uncertainty of the value, i.e. the combined uncertainty times the coverage factor $k(\alpha)$. The test is one-sided since the legal limit does not have an uncertainty. Experience has shown that the distributions of experimental data follow a log-normal rather than a normal distribution, in particular in the region of the lower legal limit. Thus, the estimate for the expanded uncertainty is added in a multiplicative way.

Taking into account the above, the decision limit for compliance is defined as

$$\bar{d}_{meas} \le d_{\lim} \cdot (1 + k(\alpha) \cdot u_{t,r}) \quad \text{(A.2)}$$

where

$k(\alpha)$ is the coverage factor for the chosen significance level (0,05) and the one sided t-test which gives a corresponding value of 1,65, assuming a large number of degrees of freedom for the combined uncertainty;

$d_{\lim}$ is the legal 0,2 µg/cm^2 /week or 0,5 µg/cm^2/week limit, respectively;

$\bar{d}_{meas}$ is the nickel release value (value d in Formula(1)). Note that $\bar{d}_{meas}$ is determined with a mean of concentration replicate measurements.

NOTE 1 For guidelines to the evaluation of uncertainty in measurement it is advised to refer to ISO/IEC Guide 98-3: “Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement (GUM 1995)”, and more specifically for analytical measurements to the EURACHEM/CITAC Guide 2012 “Quantifying Uncertainty in Analytical Measurement“. Guidance on the relationship between analytical results, the expanded measurement uncertainty and limit values are given in the EURACHEM/CITAC Guide 2007 “Use of uncertainty information in compliance assessment”.

Using this decision criterion for articles that shall show compliance with the migration limit of 0,5 µg/cm^2/week, an article will be deemed to be non-compliant when the nickel release value d (9.1) is greater than or equal to 0,88 µg/cm^2/week. For articles that shall show compliance with the migration limit of 0,2 µg/cm^2/week, an article will be deemed to be non-compliant when the nickel release value d (9.1) is greater than or equal to 0,35 µg/cm^2/week.

NOTE 2 For further information on articles made from composite materials refer to Annex D."

3 Modification to Annex B

Delete the first sentence in NOTE 1.

4 Modifications to the Bibliography

Replace [7] with:

"EURACHEM/CITAC Guide 2012 "*Quantifying Uncertainty in Analytical Measurement*", http://www.eurachem.org/index.php/publications/guides/quam"

Add the following reference:

"[11] ISO/IEC Guide 98-3: "*Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*"