ILNAS

Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN 1811:1998+A1:2008

Reference test method for release of nickel from products intended to come into direct and prolonged contact with the skin

Méthode d'essai de référence pour la libération du nickel par les produits qui sont destinés à venir en contact direct et prolongé avec la peau

Referenzprüfverfahren zur Bestimmung der Nickellässigkeit von Produkten die in direkten und länger andauernden Kontakt mit der Haut kommen

04/2008

National Foreword

This European Standard EN 1811:1998+A1:2008 was adopted as Luxembourgish Standard ILNAS-EN 1811:1998+A1:2008.

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- Participate in the design of standards
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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 1811:1998+A1

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English Version

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This European Standard was approved by CEN on 10 October 1998 and includes Amendment 1 approved by CEN on 4 February 2008.

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 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 Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

This document (EN 1811:1998+A1:2008) has been prepared by Technical Committee CEN/TC 347 “Methods for analysis of allergens”, the secretariat of which is held by DS.

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of an identical text or by endorsement, at the latest by October 2008 and conflicting national standards shall be withdrawn at the latest by October 2008.

This document includes Amendment 1 approved by CEN on 2008-02-04.

This document supersedes EN 1811:1998.

The start and finish of text introduced or altered by amendment is indicated in the text by tags A1 A1.

Annex A, B, C, D and E are informative.

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, 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.

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% - 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 articles intended to come into direct and prolonged contact with the skin in order to determine whether such items release nickel at a rate greater than 0,5 µg/cm^2/week.

2 Principle

The item to be tested for nickel release is 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.