TECHNICAL REPORT

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English Version

Screening test for the presence of nickel in articles which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin

Méthode de tri pour la présence de nickel dans les articles introduits dans les parties percées du corps humain et les produits destinés à entrer en contact direct et prolongé avec la peau

Screeningverfahren für die Nickelabgabe aus Erzeugnissen, die in durchstochene Körperteile eingeführt werden, und Erzeugnissen, die unmittelbar und länger mit der Haut in Berührung kommen

This Technical Report was approved by CEN on 24 January 2022. It has been drawn up by the Technical Committee CEN/TC 347.

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European foreword

This document (CEN/TR 12471:2022) has been prepared by Technical Committee CEN/TC 347 "Methods for analysis of allergens", the secretariat of which is held by SNV.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes CR 12471:2002.

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

Introduction

This document provides a completely revised and restructured edition of CR 12471:2002, *Screening tests for nickel release from alloys and coatings in items that come into direct and prolonged contact with the skin*.

This document has been prepared for the detection of nickel release. The described method is cost-effective. It has particular relevance in relation to nickel contact dermatitis. In order to decrease the incidence of nickel contact dermatitis, the European Commission introduced in 1994 the Nickel Directive (94/27/EC), which specified a limit value for nickel content in articles inserted into pierced parts of the human body and a limit value for nickel release from articles intended to come into direct and prolonged contact with the skin.

The Nickel Directive has been replaced by REACH regulation (EC) No 1907/2006 in 2006. According to REACH regulation Annex XVII, entry no 27, the nickel release for articles inserted into pierced parts of the human body, has to be less than 0,2 µg/cm^2/week, whereas for articles intended to come into direct and prolonged contact with the skin, it is 0,5 µg/cm^2/week or less.

European Standard EN 1811, *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*, is used to determine whether such articles are in compliance with the Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH), Annex XVII, entry no 27, as amended.

1 Scope

This document provides a screening test based upon the use of dimethylglyoxime for detecting the presence of nickel in articles that are inserted into pierced parts of the human body and those that are intended to come into direct and prolonged contact with the skin.

This screening test is suitable for manufacturers and importers as a qualitative method for detecting the presence of nickel in articles.

NOTE The reference method for the measurement of nickel release is EN 1811, or for spectacle frames and sunglasses, EN 16128.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN ISO 3696, *Water for analytical laboratory use - Specification and test methods (ISO 3696)*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

4 Principle

The method is based on the formation of a red coloured metal complex when nickel ions react with a solution of dimethylglyoxime in the presence of ammonia.

In order to increase the sensitivity of the screening test, pre-treatment with artificial sweat and heat is used to induce corrosion of the surface, simulating the influence of sweat when the article is in contact with the skin. This screening method provides a result in a short time.

5 Reagents

All reagents should be of *pro analysis* grade or better.

5.1 Deionized water, according to EN ISO 3696, grade 2.

5.2 Ammonia solution, 10 % ammonia.

This solution may be prepared from a more concentrated ammonia solution, for example, one with a mass fraction of 24 % or 30 % NH_3.

5.3 Sodium chloride, NaCl.

5.4 DL-Lactic acid, $CH_3CHOHCOOH$, > 88 % (m/m).

5.5 Urea, $CO(NH_2)_2$.