CEN REPORT

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English version

Screening tests for nickel release from alloys and coatings in items that come into direct and prolonged contact with the skin

Méthode de tri pour la libération du nickel des alliages et revêtements présents sur les articles de consommation entrant en contact direct et prolongé avec la peau Schnelltest für die Nickelabgabe aus Legierungen und Auflagen auf Gegenständen, die mit der Haut in direkte und länger andauernde Berührung kommen

This CEN Report was approved by CEN on 13 April 2002. It has been drawn up by the Technical Committee CEN/TC 283.

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Foreword

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y and associate. This document (CR 12471:2002) has been prepared by Technical Committee CEN/TC 283 "Precious metals -Applications in jewellery and associated products", the secretariat of which is held by UNI.

Introduction

This document has been developed as a simple, quick and inexpensive means for qualitatively testing for nickel release from (mainly) consumer items. It has particular relevance in relation to allergic contact dermatitis due to nickel allergy. The tests described are quick and easy to conduct and two of them are suitable for application outside of the laboratory.

European Parliament and Council Directive 94/27/EC (OJ No. L 188 of 22.7.94) has set a nickel release rate threshold of 0.5 µg/cm²/week. Although the present document will give information concerning nickel release, results obtained from its application do not constitute confirmation or otherwise of compliance with the directive. In it as app. order to show compliance with the directive, it is necessary that items are tested in accordance with European Standards EN 1810, EN 1811 or EN 12472, as appropriate, depending upon the nature of the item to be tested.

1 Scope

This document presents a screening procedure, based primarily on the use of dimethylglyoxime, for the detection of nickel release from items that come into direct and prolonged contact with the skin.

The tests provide qualitative, not quantitative, results.

NOTE - EN 1811 specifies a quantitative reference test for the release of nickel.

2 Short description of the methods

The test methods are based on the formation of a coloured complex when nickel ions come into contact with dimethylglyoxime or dithiooxamide. In order to increase the sensitivity of the method, pre-treatment with artificial sweat and heat is used to induce corrosion of the surface, simulating the influence of sweat when the item is in contact with the skin. This screening method gives a result in a short time. The result is indicative and provides guidance when evaluating items for nickel release.

3 Reagents

All reagents shall be of pro analysi grade or better.

- 3.1 Deionized water
- 3.2 Ammonia solution, about 10 % (m/m) NH₃

NOTE - This solution may be prepared from a more concentrated ammonia solution; for example, one containing 24 % or 30 % (m/m) NH₃.

- 3.3 Sodium chloride, NaCl
- 3.4 Lactic acid, CH₃CHOHCOOH, ρ = 1,21 g/ml, > 88 %
- **3.5** Urea, CO(NH₂)₂
- 3.6 Dimethylglyoxime, $C_4H_8N_2O_2$, 99 %, or test strips for the detection of nickel, containing dimethylglyoxime or other colorimetric reagent(s) with approximately equivalent selectivity and sensitivity to nickel.
- **3.7** Ethanol, C_2H_5OH , > 95 %
- **3.8** Hydrogen peroxide, H_2O_2 , approximately 30 % (m/V) solution (100 volume). (Not required for the pre-test, 5.3.4 or the field test, 5.3.6)
- 3.9 Dithiooxamide (rubeanic acid), C₂H₄N₂S₂. (Not required for the pre-test or the field test)
- **3.10** Sodium acetate trihydrate, C₂H₃NaO₂3H₂O. (Not required for the pre-test or the field test)
- 3.11 Acetic acid, glacial, C₂H₄O₂. (Not required for the pre-test or the field test)

4 Equipment

- 4.1 Flat-bottomed dish, made of glass or other non-metallic material. (Not required for the pre-test)
- 4.2 Thermometer, $(0^{\circ}\text{C} 100^{\circ}\text{C}) \pm 1^{\circ}\text{C}$