SLOVENSKI STANDARD
SIST EN 16711-3:2019

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Tekstilije - Določevanje kovin - 3. del: Določevanje sproščanja svinca z raztopino umetne sline

Textiles - Determination of metal content - Determination of lead release by artificial saliva solution

Textilien - Bestimmung von Metallen - Teil 3: Bestimmung von Bleilässigkeit mit künstlicher Spechellösung

Textiles - Détermination de la teneur en métaux - Partie 3 : Détermination de la libération de plomb dans une solution de salive artificielle

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59.060.01	Tekstilna vlakna na splošno	Textile fibres in general

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EUROPEAN STANDARD

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English Version

Textiles - Determination of metal content - Part 3: Determination of lead release by artificial saliva solution

Textiles - Détermination de la teneur en métaux - Partie 3 : Dosage du plomb libéré par une solution de salive artificielle

Textilien - Bestimmung des Metallgehaltes - Teil 3: Bestimmung der Bleilässigkeit mit Speichelsimulanzlösung

This European Standard was approved by CEN on 15 March 2019.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (EN 16711-3:2019) has been prepared by Technical Committee CEN/TC 248 “Textiles and textile products”, the secretariat of which is held by BSI.

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of an identical text or by endorsement, at the latest by November 2019, and conflicting national standards shall be withdrawn at the latest by November 2019.

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.

EN 16711 consists of the following parts, under the general title *Textiles — Determination of metal content*:

— *Part 1: Determination of metals using microwave digestion*

— *Part 2: Determination of metals extracted by acidic artificial perspiration solution*

— *Part 3: Determination of lead release by artificial saliva solution*

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: 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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

Repeated exposure to lead from mouthing of articles containing lead or its compounds can result in severe and irreversible neurobehavioural and neurodevelopmental effects to which children are particularly sensitive given that their central nervous system is still under development. The placing on the market and use of lead and its compounds in articles that are supplied to the general public, and which can be placed in the mouth by children [3][4], should therefore be prohibited if the concentration of lead (expressed as metal) in that article, or part of the article, exceeds a certain threshold. Annex XVII to Regulation (EC) No 1907/2006, column 2 of entry 63 paragraph 7, second clause [5].

The testing follows the instructions for the determination of nickel-release from materials with direct and prolonged skin contact, EN 1811. The limit value for nickel release is defined in the unit µg/cm²/week and is tested over the period of one week. Therefore, as the limit value of the present regulation applies the unit µg/cm²/h, the test period is correspondingly set to 1 h. According to the publication "*Migration protocol to estimate metal exposure from mouthing copper and tin alloy objects*" [3], the release of lead in the tested materials is mostly linear with time, thus the influence of the testing period is considered secondary.

For coated articles it should be ensured that the release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article. Such articles/materials are treated following the abrasion-test EN 12472 before the above described test procedure for lead-release.

Testing is performed using an artificial saliva solution, because "COMMISSION REGULATION (EU) 2015/628 of 22 April 2015 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH') as regards lead and its compounds", applies to materials that can be taken into the mouth by children (mouthing) [3].

Exposure from swallowing lead-containing materials is not explicitly addressed in this regulation. This type of exposure is considered in the frame of testing of toys (EN 71-3:2013+A3:2018), which is exempt from this regulation [1].

1 Scope

This document describes a testing procedure to determine the rate of lead release from all materials of textile articles.

NOTE With this test procedure it can be demonstrated that the rate of lead release from such an article or any accessible part of an article, whether coated or uncoated, does or does not exceed 0,05 µg/cm² per hour, and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article (Annex XVII of Regulation (EC) No 1907/2006, column 2 of entry 63 paragraph 7, second clause) [5].

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 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*

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 3071, *Textiles - Determination of pH of aqueous extract (ISO 3071)*

EN ISO 11885, *Water quality - Determination of selected elements by inductively coupled plasma optical emission spectrometry (ICP-OES) (ISO 11885)*

EN ISO 17294-2, *Water quality - Application of inductively coupled plasma mass spectrometry (ICP-MS) - Part 2: Determination of selected elements including uranium isotopes (ISO 17294-2)*

EN ISO 15586, *Water quality - Determination of trace elements using atomic absorption spectrometry with graphite furnace (ISO 15586)*

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:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

4 Principle

The test specimens are tested for migration in artificial saliva-solution (according to Annex A) for 1 h, using the surface-volume ratio of 1 ml artificial saliva solution per square centimetre of the sample area of the test specimen as described in EN 1811; then the saliva solution is analysed for lead.

For coated items (except coated fabrics) it has to be ensured that the release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article. Such articles/materials are treated according to EN 12472 before the above described test procedure for lead-release.

5 Safety precautions

WARNING – The use of EN 16711-3 involves a hazardous chemical. It does not purport to address all of the safety or environmental problems associated with its use. It is the responsibility of users of this document to take appropriate measures to ensure the safety and health of personnel and the environment prior to application of this document, and fulfil statutory and regulatory requirements for this purpose.

5.1 It is the user's responsibility to use safe and proper techniques in handling reagents in this test method. Consult manufacturers for specific details such as material safety data sheets and other recommendations.

5.2 Users should comply with any national and local safety regulations.

6 Reagents

Unless otherwise specified, analytical grade chemicals shall be used.

6.1 **Water**, grade 3 according to EN ISO 3696:1995

6.2 **Sodium chloride** (NaCl)

6.3 **Hydrochloric acid** (HCl) = mass fraction of 1 %

6.4 **Magnesium chloride** ($MgCl_2 \cdot 6H_2O$)

6.5 **Calcium chloride** ($CaCl_2 \cdot 2H_2O$)

6.6 **Dipotassium hydrogen phosphate** ($K_2HPO_4 \cdot 3H_2O$)

6.7 **Potassium carbonate** (K_2CO_3)

6.8 **Potassium chloride** (KCl)

6.9 **Nitric acid** (HNO_3) = mass fraction of 65 %

WARNING - Nitric acid 65 % may intensify fire; it is an oxidizer; may be corrosive to metals; causes severe skin burns and eye damage, and is corrosive to the respiratory tract.

6.10 **Artificial saliva solution**, pH-value of (6,8 ± 0,1) according to Annex A

6.11 Degreasing solution:

An appropriately diluted, neutral, commercially available cleaning agent should be used, e.g. 0,5 % by mass of aqueous solution of sodium dodecylsulphate.

6.12 Dilute nitric acid, approximate mass fraction of 5 %

6.13 Lead stock solution, with mass concentration of 1 000 mg/l

7 Apparatus and materials

7.1 pH meter with glass electrode according to EN ISO 3071

7.2 An analytical instrument capable of detecting lead in the final release solution. It is recommended that either an inductively coupled plasma optical emission spectrometer (ICP-OES, as described in EN ISO 11885), or inductively coupled plasma mass spectrometer (ICP-MS, as described in EN ISO 17294-2) or an atomic absorption spectrometer with graphite furnace (GFAAS, as described in EN ISO 15586) is used.

7.3 Water bath shaker, capable of maintaining (40 ± 2) °C and adjustable to a frequency of (60 ± 5) min^{-1}

7.4 Wax or covering lacquer, free from lead

7.5 Ruler, micrometer screw, calliper, etc.

7.6 Vessels with lids

7.7 Drum with mounting device according to EN 12472

7.8 Filter, pore-size 0,45 µm

7.9 Fluted filter (material paper), diameter 110 mm

8 Preparation of test specimens

8.1 Sampling

Accessible parts, which may be placed in the mouth by children during normal or reasonably foreseeable conditions of use, are tested. The article is cut to yield homogeneous test specimens. Sampling is carried out as described in EN 1811. A minimum of three test specimens from the same batch shall be tested wherever possible.

Very high lead concentrations in the core of a sample can permeate coatings. To avoid false-positive results, the cutting should be minimized (see 8.4).

NOTE This document covers textiles and textile products. Textiles are mainly very flexible and it is reasonable to assume that any part of a fabric is accessible and can be sucked / mouthed by a baby or child. Therefore, there is no restriction on the size of product in this case. Accessories can be rigid (buttons, zippers, etc.). It is considered that, in these cases, an article or accessible part of an article can be placed in the mouth by children if it is smaller than 5 cm in one dimension or has a detachable or protruding part of that size.

8.2 Determination of the specimen surface area

Determination of the specimen surface area is carried out as described in EN 1811.