

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

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

See Eesti standard EVS-EN 16711-3:2019 sisaldab Euroopa standardi EN 16711-3:2019 ingliskeelset teksti.	This Estonian standard EVS-EN 16711-3:2019 consists of the English text of the European standard EN 16711-3:2019.
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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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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-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
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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of an identical text or by endorsement, at the latest by November 2019, and conflicting national standards shall be withdrawn at the latest by November 2019.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  $\mu\text{g}/\text{cm}^2/\text{week}$  and is tested over the period of one week. Therefore, as the limit value of the present regulation applies the unit  $\mu\text{g}/\text{cm}^2/\text{h}$ , 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/cm<sup>2</sup> 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>