

Child use and care articles - Method for determining the release of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

See Eesti standard EVS-EN 12868:2017 sisaldab Euroopa standardi EN 12868:2017 ingliskeelset teksti.	This Estonian standard EVS-EN 12868:2017 consists of the English text of the European standard EN 12868:2017.
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English Version

Child use and care articles - Method for determining the  
release of N-nitrosamines and N-nitrosatable substances  
from elastomer or rubber teats and soothers

Articles de puériculture - Méthode pour déterminer la  
libération de N-nitrosamines et de substances N-  
nitrosables par les tétones et les sucettes en élastomère  
ou en caoutchouc

Artikel für Säuglinge und Kleinkinder - Verfahren zur  
Bestimmung der Abgabe von N-Nitrosaminen und N-  
nitrosierbaren Stoffen aus Babysaugern aus  
Elastomeren und Gummi

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## European foreword

This document (EN 12868:2017) has been prepared by Technical Committee CEN/TC 252 "Child use and care articles", the secretariat of which is held by AFNOR.

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of an identical text or by endorsement, at the latest by July 2017, and conflicting national standards shall be withdrawn at the latest by July 2017.

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 EN 12868:1999.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

Compared to EN 12868:1999, this document contains the following significant changes:

- The common practice to perform at least double determinations has been made a requirement, including the preparation of samples.
- Sample preparation has been defined and simplified, reducing this source of interlaboratory variation.
- The pre-boiling and migration steps have been separated for the determination of N-nitrosamines and of N-nitrosatable substances, allowing use of the same vessels and avoiding the possible loss of migrated substances. Amounts of sample have been adjusted, increasing the sample mass for the determination of N-nitrosatable substances.
- Extraction of N-nitrosamines from the aqueous migrates has been restricted to one method, reducing interlaboratory variability. A rinsing step has been introduced to avoid variability due to possible loss of analytes.
- The calculation of results has been revised including a repeatability requirement for multiple determinations and taking into account state of the art analytical procedures.
- The confirmation of N-nitrosamines and application of analytical tolerances have been clarified including a N-nitrosamine specific adjustment as suggested by the validation trial.

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

It has been shown that feeding teats and soothers made of elastomer or rubber may release N-nitrosamines and substances capable of being converted into N-nitrosamines (N-nitrosatable substances). The Scientific Committee for Food of the European Union has given the opinion that N-nitrosamines and N-nitrosatable substances may endanger human health owing to their toxicity [5]. Hence in 1993, the European Commission issued Directive 93/11/EEC [1] controlling rubber and elastomeric teats and soothers releasing these substances. The Directive also provided basic rules for determining the release of these substances and criteria for the method of analysis to be adopted.

The purpose of this European Standard is to provide a detailed analytical method for the identification and determination of N-nitrosamines and N-nitrosatable substances released from teats and soothers in order that compliance with the requirements of Directive 93/11/EEC may be tested.

This method has been validated.

The testing laboratories should take special care to observe occupational health and safety standards. Persons using this European Standard should be familiar with normal laboratory practice. This European Standard does not purport to address all of the safety problems, if any, associated with its use. It is the responsibility of the user to establish appropriate safety and health practices and to ensure compliance with any national regulatory conditions.



## 1 Scope

This European Standard specifies the method for determining N-nitrosamines and N-nitrosatable substances released from elastomer or rubber teats in contact with artificial saliva salt solution for testing compliance with Directive 93/11/EEC.

## 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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)*

EN ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025)*

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

### 3.1

#### **teat**

flexible elastomeric part designed to be placed in the mouth

### 3.2

#### **soother**

article which includes a teat and which is intended to satisfy the non-nutritive sucking need of children

Note 1 to entry: Soothers are also known as pacifiers or babies' dummies.

### 3.3

#### **feeding teat**

any teat that permits a child to obtain food or drink

### 3.4

#### **elastomer**

material which undergoes substantial, elastic (fully reversible) deformation when put under stress and consisting of three-dimensional networks of cross-linked flexible polymers

Note 1 to entry: The cross-links are chemical bonds generated by curing in rubbers (like natural rubber or synthetic rubber including silicones) or physical, thermo-reversible fixation points in thermoplastic elastomers (TPE) or the combination of both (TPEV).

### 3.5

#### **rubber**

types of elastomer

### 3.6

#### **N-nitrosamine**

substance characterised by the N-nitroso functional group, N-NO, usually formed by the reaction of an amine with a nitrosating agent, e.g. nitrite, at acidic pH