

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

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## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 12868:2000 sisaldab Euroopa standardi EN 12868:1999 + AC:2002 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 18.02.2000 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 12868:2000 consists of the English text of the European standard EN 12868:1999 + AC:2002.</p> <p>This document is endorsed on 18.02.2000 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p><b>Käsitlusala:</b></p> <p>This standard specifies methods for the isolation identification and determination of N-nitrosamines and N-nitrosatable substances released by artificial saliva from elastomer or rubber teats and soothers.</p>	<p><b>Scope:</b></p> <p>This standard specifies methods for the isolation identification and determination of N-nitrosamines and N-nitrosatable substances released by artificial saliva from elastomer or rubber teats and soothers.</p>
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ICS 97.190

Võtmesõnad:

**English version**

Child use and care articles

**Methods for determining the release of  
N-nitrosamines and N-nitrosatable substances  
from elastomer or rubber teats and soothers**

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

Artikel für Säuglinge und Klein-  
kinder – Verfahren zur Bestimmung  
der Abgabe von N-Nitrosaminen und  
N-nitrosierbaren Stoffen aus  
Flaschen- und Beruhigungssaugern  
aus Elastomeren oder Gummi

This European Standard was approved by CEN on 1999-08-21.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

The European Standards exist 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 Central Secretariat has the same status as the official versions.

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**CEN**

European Committee for Standardization  
Comité Européen de Normalisation  
Europäisches Komitee für Normung

**Central Secretariat: rue de Stassart 36, B-1050 Brussels**

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## Foreword

This European Standard 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 March 2000, and conflicting national standards shall be withdrawn at the latest by March 2000.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland 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. Hence in 1993, the European Commission issued a Directive (93/11/EEC) controlling rubber and elastomeric soothers and feeding teats releasing these substances. The Directive also provided basic rules for determining the release of the substances and criteria for the method of determination to be adopted.

The purpose of this European Standard is to provide detailed analytical methods 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 determined.

The method has been validated by a collaborative trial in which twelve laboratories participated. The trial concentrated on products which release N-Nitrosodimethylamine, N-Nitrosodiethylamine, N-Nitrosodibutylamine and N-Nitrosodibenzylamine. The results have also been used to consider amendment of the Analytical Correction (clause 9).

## 1 Scope

This European Standard specifies methods for the isolation, identification and determination of N-Nitrosamines and N-Nitrosatable substances released by artificial saliva from elastomer or rubber teats and soothers.

## 2 Normative references

This European Standard incorporates by dated or undated references, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to, or revisions of, any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 45001, General criteria for the operation of testing laboratories.

EN ISO 3696, Water for analytical laboratory use - Specification and test methods (ISO 3696:1987).

## 3 Terms and definitions

For the purpose of this standard, the following terms and definitions apply :

### 3.1

#### **soother**

article used to satisfy sucking needs and pacify children

NOTE Soothers are also known as pacifiers or babies' dummies.

### 3.2

#### **teat**

flexible elastomeric or rubber part of the soother designed to be placed in the mouth. Alternatively it may be a feeding teat

### 3.3

#### **feeding teat**

substitute nipple that when attached to a container holding a fluid permits a child to obtain the fluid by sucking

### 3.4

#### **rubber**

material with high extensibility coupled with an ability to recover, essentially completely, from that extension in a short period of time - a material which is highly elastic

### 3.5

#### **elastomer**

material which has the same highly elastic properties as rubber throughout a defined temperature range, but with different chemical structure

### 3.6

#### **N-Nitrosamine**

substance characterised by the -N-N=O functional group, usually formed by the reaction of an amine (primarily a secondary amine) with a nitrosating agent, e.g. nitrite, at acidic pH

### 3.7

#### **N-Nitrosatable substance**

substance which when released into the test solution undergoes nitrosation to form a N-Nitrosamine under specified conditions