

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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British Standard

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National foreword

This British Standard is the official English language version of EN 12868:1999, including Corrigendum February 2002. It supersedes BS 7115-1 and BS 7115-2:1988 which are withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CW/42, Babies dummies, bottles and teats, which has the responsibility to:

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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 Kleinkinder - 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 21 August 1999.

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Contents	Page
Foreword	3
Introduction	4
1 Scope	5
2 Normative references	5
3 Terms and definitions	5
4 Principle	6
5 Reagents	6
6 Apparatus	8
7 Procedure	10
8 Interpretation of results	12
9 Analytical tolerances	13
10 Confirmation of <i>N</i> -nitrosamines detected	14
11 Test report	14
Bibliography	15

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of an identical text or by endorsement, at the latest by March 2000, and conflicting national standards shall be withdrawn at the latest by March 2000.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 analytical tolerances (clause 9).