

Child use and care articles - Methods for determining the release of N-Nitrosamines and N-Nitrosatable substances from elastomer or rubber teats and soothers

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

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 en caoutchouc

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release of N-Nitrosamines and N-Nitrosatable substances from
elastomer or rubber teats and soothers

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nitrosierbaren Stoffen aus Flaschen- und
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This European Standard was approved by CEN on 21 August 1999.

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.

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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



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COMITÉ EUROPÉEN DE NORMALISATION
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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of an identical text or by endorsement, at the latest by March 2000, and conflicting national standards shall be withdrawn at the latest by March 2000.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.

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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).

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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 feat

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

4 Principle

N-Nitrosamines and N-Nitrosatable substances are extracted into a nitrite-containing artificial saliva salt solution. After concentration and, in the case of N-Nitrosatable substances, after conversion, the final test solutions are examined for N-Nitrosamines by gas chromatography (GC) employing a chemiluminescence detector or other suitable validated analytical technique. The analysis shall be carried out in an atmosphere free from volatile N-Nitrosamines and N-Nitrosatable substances. The N-Nitrosamine and N-Nitrosatable substances released are expressed as N-Nitrosamines released in micrograms per kilogram ($\mu\text{g}/\text{kg}$) of the sample.

WARNING : N-Nitrosamines can endanger human health owing to their toxicity. Test laboratories should pay particular attention to the requirements of health and safety at work legislation.

5 Reagents

5.1 Unless otherwise specified, all chemicals shall be of analytical grade and distilled water, or water of equivalent purity conforming to at least grade 3 of EN ISO 3696.

5.2 Sodium hydrogen carbonate.

5.3 Sodium chloride.

5.4 Potassium carbonate.

5.5 Sodium nitrite.

NOTE This reagent can have a shelf-life of only about two years.

5.6 Hydrochloric acid solution, $c(\text{HCL}) = 0,1 \text{ mol/l}$.

5.7 Sodium hydroxide solution, $c(\text{NaOH}) = 0,1 \text{ mol/l}$.

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5.8 Artificial saliva salt solution.

Dissolve 4,2 g of the sodium hydrogen carbonate (5.2), 0,5 g of the sodium chloride (5.3), 0,2 g of the potassium carbonate (5.4) and 30 mg of the sodium nitrite (5.5) in water and dilute to 900 ml with water. Adjust to pH 9,0 if necessary by adding the hydrochloric acid solution (5.6) or sodium hydroxide solution (5.7) drop by drop. Transfer into a 1 l volumetric flask and dilute to the mark with water.

NOTE This solution can have a shelf-life of not more than two weeks when stored in a well stoppered bottle having a minimum air space above the liquid.

5.9 Dichloromethane, distilled in glass and checked for the absence of nitrosamines and nitrosatable substances (7.5).

5.10 Kieselguhr, from liquid-liquid extraction, spec. surface $1 \text{ m}^2/\text{g}$, pore size 3 000 nm to 8 500 nm, particle size $150 \mu\text{m}$ to $650 \mu\text{m}$; heated to $200 \text{ }^\circ\text{C}$ for 1 h, cooled and washed with dichloromethane (5.9).

NOTE An alternative separation material can be employed provided it has been validated against Kieselguhr.

5.11 n-hexane.

5.12 Hydrochloric acid solution, $c(\text{HCL}) = 1 \text{ mol/l}$.

5.13 Sodium hydroxide solution, $c(\text{NaOH}) = 1 \text{ mol/l}$.

5.14 Purified nitrogen.

5.15 Anti-bumping granules.

5.16 Sintered glass frits for columns (6.3 and 6.4).

5.17 Acetone, or other suitable solvent.

5.18 Standard solutions of N-Nitrosamines

Prepare a solution(s) in the n-hexane (5.11) of known amounts of the N-Nitrosamines to be determined within the concentration range of 100 ng/ml to 300 ng/ml. Alternatively, certified solutions may be used to achieve the same concentration range.

The following N-Nitrosamines have been identified as of concern in rubber and elastomeric teats and soothers. However, this list is not exhaustive :

N-Nitrosodimethylamine (NDMA)

N-Nitrosodiethylamine (NDEA)

N-Nitrosodipropylamine (NDPA)

N-Nitrosodibutylamine (NDBA)

N-Nitrosopiperidine (NPIP)

N-Nitrosopyrrolidine (NPYR)

N-Nitrosomorpholine (NMOR)

N-Nitrosodibenzylamine (NDBzA)

N-Nitrosodiisononylamine (NDiNA), i.e. N-Nitroso 3,5,5-trimethylhexylamine

N-Nitroso N-methyl N-phenylamine (NMPHA)

N-Nitroso N-ethyl N-phenylamine (NEPHA)

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Should other N-Nitrosamines be detected, they should also be determined as described.

5.19 Internal standard solution of N-Nitrosodiisopropylamine (NDiPA), free from other N-Nitrosamines, 200 ng/ml in the acetone or other suitable solvent (5.17).

NOTE N-Nitrosamines are degraded by ultra-violet light. Exposure of extracts or standards to sources such as sun-light or fluorescent tube light should be avoided. The samples and standards should be protected by wrapping in aluminium foil and stored in the dark at a temperature of less than 5 °C.

5.20 Anhydrous sodium sulfate (granular) or suitable Whatman phase separating filter.

Pre-wash 30 g of sodium sulfate with 25 ml of the dichloromethane (5.9).

5.21 Ammonia solution, $c(\text{NH}_3) = 0,1 \text{ mol/l}$.

5.22 Sand, acid washed and calcined.