

# SVENSK STANDARD

## SS-EN 12868/AC:2013



Fastställt/Approved: 2013-10-22  
Publicerad/Published: 2014-05-15  
Utgåva/Edition: 1  
Språk/Language: engelska/English  
ICS: 97.190

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### **Barnartiklar – Metoder för bestämning av avgivning av N-nitrosaminer och liknande substanser från elastomerer eller gumminappar**

**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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Europastandarden EN 12868:1999/AC:2002 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 12868:1999/AC:2002.

The European Standard EN 12868:1999/AC:2002 has the status of a Swedish Standard. This document contains the official English version of EN 12868:1999/AC:2002.

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Standarden är framtagen av kommittén för Barnartiklar, SIS/TK 404.

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EUROPEAN STANDARD

**EN 12868:1999/AC**

NORME EUROPÉENNE

EUROPÄISCHE NORM

February 2002

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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 télines 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 corrigendum becomes effective on 27 February 2002 for incorporation in the three official language versions of the EN.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**Management Centre: rue de Stassart, 36 B-1050 Brussels**

## GGIEN 12868:1999/AC:2002 (E)

### English

The corrections are bold faced.

Contents

read: "9 Analytical **tolerances**"

Introduction

Third paragraph, last sentence

read: "The results have also been used to consider **analytical tolerances** (clause 9)."

5.18 Standard solution of *N*-Nitrosamines

last sentence

read: "...they should also be determined **and reported as prescribed.**"

5.19

read: "...other *N*-Nitrosamines, **approximately** 200 ng/ml in acetone..."

7.1.1

delete the first sentence. Replace the second sentence by "**Weigh a minimum of 40 g of feeding teats or teats removed from soothers.**"

7.1.2

third line

read: "...closed flask at  $(40 \pm 2) ^\circ\text{C}$  for 24 h ( **$\pm 30$  min**) in the oven (6.2)."

7.2.9

third line

read: "... in the water bath (6.6), **or equivalent**, starting at  $(40 \pm 2) ^\circ\text{C}$ ..."

8.1.2

NOTE last line

read: "analytical **tolerance** in clause 9."

8.2.2

NOTE last line

read: "analytical **tolerance** in clause 9."

9 Analytical corrections

Delete the whole clause 9 and replace it by the following one

#### 9 Analytical tolerances

9.1 Any analytical results in clause 8 which are above the limits specified in 8.1.2 and 8.2.2 shall be subjected to the analytical tolerances in 9.2 to give the calculated analytical result.

9.2 Analytical tolerance for <i>N</i> -Nitrosamines	0,01 mg/kg
Analytical tolerance for <i>N</i> -Nitrosatable substances	0,1 mg/kg

NOTE The analytical tolerances are required to take into account the inherent variability in measurement shown by the interlaboratory trials.

9.3 Products are deemed to comply with Directive 93/11/EEC if the calculated analytical result is less than the limits specified in 8.1.2 and 8.2.2.

#### EXAMPLE

Analytical result for *N*-Nitrosamines, 0,018 mg/kg

Analytical tolerance 0,01 mg/kg

Calculated analytical result = 0,018 mg/kg – 0,01 mg/kg = 0,008 mg/kg.

This would be deemed as complying with Directive 93/11/EEC (*N*-Nitrosamines limit, 0,01 mg/kg).

11 Test report

11.1 third line

read: "...Preferably, **both analytical and calculated** analytical results for ..."

# Anteckningar/Notes

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