Mänguasjade ohutus. Osa 12: N-nitrosamiinid ja Nnitrosamiinideks muutuvad ained

Safety of toys - Part 12: N-nitrosamines and N-2: 3es nitrosatable substances



# **EESTI STANDARDI EESSÕNA**

### **NATIONAL FOREWORD**

	This Estonian standard EVS-EN 71-12:2013 consists of the English text of the European standard EN 71-
teksti.	12:2013.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
	Date of Availability of the European standard is 05.06.2013.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile <a href="mailto:standardiosakond@evs.ee">standardiosakond@evs.ee</a>.

ICS 97.200.50

#### Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega: Aru 10, 10317 Tallinn, Eesti; <a href="www.evs.ee">www.evs.ee</a>; telefon 605 5050; e-post <a href="mailto:info@evs.ee">info@evs.ee</a>

#### The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation: Aru 10, 10317 Tallinn, Estonia; www.evs.ee; phone 605 5050; e-mail info@evs.ee

# EUROPEAN STANDARD

EN 71-12

# NORME EUROPÉENNE

**EUROPÄISCHE NORM** 

June 2013

ICS 97.200.50

# **English Version**

# Safety of toys - Part 12: N-Nitrosamines and N-nitrosatable substances

Sécurité des jouets - Partie 12: N-Nitrosamines et substances N-nitrosables

Sicherheit von Spielzeug - Teil 12: N-Nitrosamine und Nnitrosierbare Stoffe

This European Standard was approved by CEN on 29 May 2013.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Cont	tents	Page
Forow	ord	1
	uction	
11111 OUI	Scope	
1		
2	Normative references	
3	Terms and definitions	7
4	Requirements	8
4.1 4.2	Requirements for finger paints	
	Principle	
5		
6 6.1	Reagents and apparatusReagents	
6. 1 6. 2	Standards	
6.3	Apparatus	
7	Sample preparation	11
7.1	General	
7.2 7.2.1	Finger paints	
7.2.1 7.2.2	N-nitrosamines	
7.3	Elastomers	
7.3.1	Sample preparation for balloons	
7.3.2	Sample preparation for other toys or parts of toys than balloons	12
7.3.3 7.3.4	NitrosationPreparation of solution for determination of N-nitrosamines by HPLC-MS/MS	13 13
8	Methods of analysis	
о В.1	General	
8.2	HPLC chromatographic conditions	13
8.3	MS/MS conditions  Confirmation of detected <i>N-nitrosamines</i>	
8.4		
9 9.1	Calculation of results for <i>N-nitrosamines</i> and <i>N-nitrosatable substances</i>	16
9.1.1	General	
9.1.2	N-nitrosamines	16
9.1.3	N-nitrosatable substancesElastomers	
9.2 9.2.1	General	
9.2.2	N-nitrosamines	
9.2.3	N-nitrosatable substances	18
10	Quality	
10.1	Finger paints	
10.1.1 10.1.2	Repeatability, reproducibility and measurement uncertainty	
10.1.2	Elastomers	19
10.2.1	Repeatability, reproducibility and measurement uncertainty	19
10.2.2	Limits of detection and quantification	
11	Test report	20
Annex	A (informative) Background and rationale for this European Standard	
<b>A</b> .1	Requirements for finger paints (see 4.1)	22

A.2 Requirements for elastomers (see 4.2)	
A.3 Avoidance <i>N-nitrosamines</i> in <i>finger paints</i>	22
A.5 Reference to other standards and relevant deviations	
A.6 Conditions for nitrosation	
A.7 NDELA in balloons	
A.8 Selection of N-nitrosamines specified in this standard	
Annex B (informative) Sample storage conditions	
Annex C (informative) A-deviations	25
Annex ZA (informative) Relationship between this European Standard and the Essent Requirements of EU Directive 2009/48/EC	tial 26
Bibliography	
Requirements of EU Directive 2009/48/EC	

# **Foreword**

This document (EN 71-12:2013) has been prepared by Technical Committee CEN/TC 52 "Safety of toys", the secretariat of which is held by DS.

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 December 2013, and conflicting national standards shall be withdrawn at the latest by December 2013.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

This European Standard constitutes the 12<sup>th</sup> part of the European Standard on safety of toys.

This European Standard for safety of toys consists of the following parts:

- Part 1: Mechanical and physical properties:
- Part 2: Flammability;
- Part 3: Migration of certain elements;
- Part 4: Experimental sets for chemistry and related activities
- Part 5: Chemical toys (sets) other than experimental sets;
- Part 7: Finger paints Requirements and test methods;
- Part 8: Activity toys for domestic use;
- Part 9: Organic chemical compounds Requirements;
- Part 10: Organic chemical compounds Sample preparation and extraction;
- Part 11: Organic chemical compounds Methods of analysis;
- Part 12: N-nitrosamines and N-nitrosatable substances;
- Part 13: Olfactory board games, gustative board games, cosmetic kits and gustative kits;
- Part 14: Trampolines for domestic use.

NOTE 1 In addition to the above parts of EN 71, the following guidance documents have been published: CEN Report, CR 14379, Classification of toys — Guidelines, CEN Technical Report CEN/TR 15071, Safety of toys — National translations of warnings and instructions for use in EN 71, and CEN Technical Report CEN/TR 15371, Safety of toys — Replies to requests for interpretation of EN 71-1, EN 71-2, and EN 71-8.

NOTE 2 Words in *italics* are defined in Clause 3 (Terms and definitions).

J to s are b. c., Denne. ry, Iceland. i. .
Ania, Slovakia, b. 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,

# Introduction

There are ongoing developments in the following area:

 the influence of the mouthing behaviour (mouthing time and sucking/chewing) on the migration out of teethers and other elastomers than balloons.

WARNING — N-nitrosamines can endanger human health owing to their toxicity. Persons using this ria. .fety, .ate safe. 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 requirements and test methods for *N-nitrosamines* and *N-nitrosatable substances* for:

- toys and parts of toys made from *elastomers* and intended for use by children under 36 months;
- toys and parts of toys made from elastomers and intended to be placed in the mouth;
- finger paints for children under 36 months.

EXAMPLES Examples of toys made from elastomers are balloons and teethers.

#### 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)

# 3 Terms and definitions

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

#### 3.1

#### finger paint

paste and/or jelly like, coloured mixture specially designed for children to apply directly to suitable surfaces with the fingers and hands

Note 1 to entry: In addition to water, *finger paints* essentially consist of colorants, binders, preservatives and embittering agent and may additionally contain extenders, humectants and surfactants.

[SOURCE: prEN 71-7:2012, 3.1]

#### 3.2

# 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 can be chemical bonds in rubbers (like natural rubber, synthetic rubber and silicones) or physical, thermo-reversible fixation points in thermoplastic *elastomers* (TPE) or the combination of both (TPE-V).

### 3.3

#### N-nitrosamine

substance characterised by the -N-N=O functional group, usually formed by the reaction of an amine with a nitrosating agent at acidic pH

Note 1 to entry: The reacting amines primarily are secondary amines.

Note 2 to entry: An example for a nitrosating agent is nitrite.

#### 3.4

#### N-nitrosatable substance

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