

## საქართველოს სტანდარტი

---

სათამაშოების უსაფრთხოება - ნაწილი 12: ამინური აზოტების და  
კარცენოგენების შემადგენლობები

საქართველოს სტანდარტებისა და მეტროლოგიის  
ეროვნული სააგენტო  
თბილისი

საინფორმაციო მონაცემები

1 შემუშავებულია საქართველოს სტანდარტების და მეტროლოგიის ეროვნული სააგენტოს სტანდარტების დეპარტამენტის მიერ

2 დამტკიცებულია და შემოღებულია სამოქმედოდ საქართველოს სტანდარტების და მეტროლოგიის ეროვნული სააგენტოს 2019 წლის 22 აგვისტოს № 46 განკარგულებით

3 მიღებულია გარეკანის თარგმნის მეთოდით სტანდარტიზაციის ევროპული კომიტეტის სტანდარტი ენ 71-12:2013 „სათამაშოების უსაფრთხოება - ნაწილი 12: ამინური აზოტების და კარცენოგენების შემადგენლობები“

4 პირველად

5 რეგისტრირებულია საქართველოს სტანდარტების და მეტროლოგიის ეროვნული სააგენტოს რეესტრში: 2019 წლის 22 აგვისტო №268-1.3-014939

დაუშვებელია წინამდებარე სტანდარტის სრული ან ნაწილობრივი კვლავწარმოება, ტირაჟირება და გავრცელება სსიპ საქართველოს სტანდარტებისა და მეტროლოგიის ეროვნული სააგენტოს ნებართვის გარეშე

საინფორმაციო ნაწილი. სრული ტექსტის სანახავად შეიძინეთ სტანდარტი.

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 N-nitrosierbare 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

Contents

Page

Foreword.....4

Introduction .....6

1 Scope.....7

2 Normative references.....7

3 Terms and definitions .....7

4 Requirements .....8

4.1 Requirements for *finger paints*.....8

4.2 Requirements for *elastomers* .....8

5 Principle.....9

6 Reagents and apparatus .....9

6.1 Reagents.....9

6.2 Standards .....10

6.3 Apparatus .....10

7 Sample preparation.....11

7.1 General .....11

7.2 Finger paints .....11

7.2.1 N-nitrosamines.....11

7.2.2 N-nitrosatable substances.....11

7.3 Elastomers.....12

7.3.1 Sample preparation for balloons.....12

7.3.2 Sample preparation for other toys or parts of toys than balloons.....12

7.3.3 Nitrosation.....13

7.3.4 Preparation of solution for determination of N-nitrosamines by HPLC-MS/MS .....13

8 Methods of analysis .....13

8.1 General .....13

8.2 HPLC chromatographic conditions.....13

8.3 MS/MS conditions .....14

8.4 Confirmation of detected *N-nitrosamines*.....15

9 Calculation of results for *N-nitrosamines* and *N-nitrosatable substances*.....16

9.1 Finger paint .....16

9.1.1 General .....16

9.1.2 N-nitrosamines.....16

9.1.3 N-nitrosatable substances.....17

9.2 Elastomers.....17

9.2.1 General .....17

9.2.2 N-nitrosamines.....18

9.2.3 N-nitrosatable substances.....18

10 Quality .....19

10.1 Finger paints .....19

10.1.1 Repeatability, reproducibility and measurement uncertainty .....19

10.1.2 Limits of detection (LOD) and quantification (LOQ) .....19

10.2 Elastomers.....19

10.2.1 Repeatability, reproducibility and measurement uncertainty .....19

10.2.2 Limits of detection and quantification .....20

11 Test report .....20

Annex A (informative) Background and rationale for this European Standard.....22

A.1 Requirements for *finger paints* (see 4.1).....22

საინფორმაციო ნაწილი. სრული ტექსტის სანახავად შეიძინეთ სტანდარტი.

A.2	Requirements for <i>elastomers</i> (see 4.2).....	22
A.3	Avoidance <i>N-nitrosamines</i> in <i>finger paints</i> .....	22
A.4	Explanation for decision to do static migration for <i>elastomers</i> .....	22
A.5	Reference to other standards and relevant deviations.....	23
A.6	Conditions for nitrosation.....	23
A.7	NDELA in balloons .....	23
A.8	Selection of N-nitrosamines specified in this standard.....	23
<b>Annex B (informative) Sample storage conditions .....</b>		<b>24</b>
<b>Annex C (informative) A-deviations.....</b>		<b>25</b>
<b>Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 2009/48/EC .....</b>		<b>26</b>
<b>Bibliography.....</b>		<b>27</b>

## 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).

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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

## 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 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.**