

STN	Bezpečnosť hračiek. Časť 12: N-nitrózoamíny a N-nitrózovateľné látky.	STN EN 71-12 94 3094
------------	--	--

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 05/17

Obsahuje: EN 71-12:2016

Oznámením tejto normy sa ruší
STN EN 71-12 (94 3094) z februára 2014

124740

Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2017
Podľa zákona č. 264/1999 Z. z. o technických požiadavkách na výrobky a o posudzovaní zhody a o zmene a doplnení niektorých zákonov v znení neskorších predpisov sa slovenská technická norma a časti slovenskej technickej normy môžu rozmnožovať alebo rozširovať len so súhlasom slovenského národného normalizačného orgánu.

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 71-12

December 2016

ICS 97.200.50

Supersedes EN 71-12:2013

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 30 October 2016.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

European foreword.....	4
1 Scope	6
2 Normative references	6
3 Terms and definitions	6
4 Requirements	7
4.1 Requirements for finger paints.....	7
4.2 Requirements for elastomers	7
5 Principle	8
6 Reagents and apparatus	8
6.1 Reagents	8
6.2 Standards	9
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	12
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	14
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 Method performance	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	21
	Annex A (informative) Background and rationale for this European Standard	22
A.1	Definition of elastomer.....	22
A.2	Requirements for finger paints (see 4.1)	22
A.3	Requirements for elastomers (see 4.2)	23
A.4	Avoidance N-nitrosamines in finger paints.....	24
A.5	Explanation for decision to do static migration for elastomers and for the specified migration times.....	24
A.6	Reference to other standards and relevant deviations	25
A.7	Conditions for nitrosation	25
A.8	NDELA in balloons	26
A.9	Selection of N-nitrosamines specified in this standard	26
	Annex B (informative) Significant technical changes between this European Standard and the previous version.....	27
	Annex C (informative) A-deviations.....	29
	Annex ZA (informative) Relationship between this European Standard and the essential requirements of EU Directive 2009/48/EC aimed to be covered	30
	Bibliography	31

European foreword

This document (EN 71-12:2017) 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 June 2017, and conflicting national standards shall be withdrawn at the latest by June 2017.

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

This document supersedes EN 71-12:2013.

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 2009/48/EC.

For relationship with EU Directive 2009/48/EC, see informative Annex ZA, which is an integral part of this document.

Additional information on the rationale for various requirements is given in Annex A. Annex B provides details of significant technical changes between this European Standard and the previous edition.

This European Standard constitutes the 12th 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 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 (all parts), *Safety of toys — Interpretations*.

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.

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.

EXAMPLE Examples of toys made from *elastomers* are balloons and teethingers.

NOTE With regard to *elastomers*, up to now *N-nitrosamines* and *N-nitrosatable substances* have mainly been detected in vulcanized materials.

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)*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN