



**SLOVENSKI STANDARD**  
**SIST EN 71-12:2017**

**01-april-2017**

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**SIST EN 71-12:2013**

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**Varnost igráč - 12. del: N-nitrozamini in N-nitrozabilne snovi**

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

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

Sécurité des jouets - Partie 12 : N-Nitrosamines et substances N-nitrosables  
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**Ta slovenski standard je istoveten z: ~~SIST EN 71-12:2016~~ EN 71-12:2016**

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**ICS:**

97.200.50 Igrače

Toys

**SIST EN 71-12:2017**

**en,fr,de**

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
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**EN 71-12**

December 2016

ICS 97.200.50

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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.

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

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

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**EN 71-12:2016 (E)****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.

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**EN 71-12:2016 (E)****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 teethers.

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)*

**3 Terms and definitions**

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

**3.1**  
**finger paint**  
aqueous semi-solid or liquid, coloured mixture specially designed for children to apply directly to suitable surfaces with the fingers and hands

[SOURCE: EN 71-7:2014, definition 3.1]

**3.2**  
**elastomer**

flexible cross-linked macro-molecular material which returns rapidly to approximately its initial dimensions and shape after substantial deformation by stress and release of the stress at room temperature

Note 1 to entry: Not all elastomers are likely to contain *N-nitrosamines* and *N-nitrosatable substances*. For further guidance on possible sources of *N-nitrosamines* and *N-nitrosatable substances* in elastomers the term elastomer and other related aspects see A.1.

[SOURCE: EN ISO 472:2013, 2.327, modified: the phrases “flexible cross-linked”, “approximately” and “at room temperature” and note 1 to entry added and the phrase “a weak” deleted]

**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

## 4 Requirements

### 4.1 Requirements for finger paints

The concentration of *N-nitrosamines* in *finger paints* shall not exceed 0,02 mg/kg when tested in accordance with 7.2 and Clause 8, calculated as sum of all detected *N-nitrosamines* according to 9.1.

The migration of *N-nitrosatable substances* from *finger paints* shall not exceed 1 mg/kg of toy material, calculated as sum of all detected *N-nitrosamines* after nitrosation.

At least the substance in Table 1 shall be determined in *finger paint*. If there are indications of the presence of other *N-nitrosamines*, they shall also be determined.

**Table 1 — List of N-nitrosamines in finger paints**

Name of the substance	CAS number	Abbreviation
N-nitrosodiethanolamine	1116-54-7	NDELA

### 4.2 Requirements for elastomers

The migration of *N-nitrosamines* (calculated as sum of all detected *N-nitrosamines* according to 9.2) and of *N-nitrosatable substances* (calculated as sum of all detected *N-nitrosamines* after nitrosation) from toys or parts of toys shall not exceed the limit values specified in Table 2 when tested in accordance with 7.3 and Clause 8.

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**Table 2 — Limit values for elastomers**

Product type	N-nitrosamines mg/kg	N-nitrosatable substances mg/kg
a) toys intended for use by children under 36 months and intended or likely to be placed into the mouth	0,01	0,1
b) toys intended for use by children under 36 months not covered by a)	0,05	1
c) toys intended for use by children of 36 months and over and intended to be placed into the mouth	0,05	1
d) balloons	0,05	1

At least the substances in Table 3 shall be determined in *elastomers*. If there are indications of the presence of other *N-nitrosamines* they shall also be determined.

Table 3 — List of N-nitrosamines in elastomers

Name of the substance	CAS number	Abbreviation
N-nitrosodiethanolamine	1116-54-7	NDELA
N-nitrosodimethylamine	62-75-9	NDMA
N-nitrosodiethylamine	55-18-5	NDEA
N-nitrosodipropylamine	621-64-7	NDPA
N-nitrosodiisopropylamine	601-77-4	NDiPA
N-nitrosodibutylamine	924-16-3	NDBA
N-nitrosodiisobutylamine	997-95-5	NDiBA
N-nitrosodiisononylamine (N-Nitroso-N,N-di(3,5,5-trimethylhexyl)amine))	1207995-62-7	NDiNA
N-nitrosomorpholine	59-89-2	NMOR
N-nitrosopiperidine	100-75-4	NPIP
N-nitrosodibenzylamine	5336-53-8	NDBzA
N-nitroso-N-methyl-N-phenylamine	614-00-6	NMPhA
N-nitroso-N-ethyl-N-phenylamine	612-64-6	NEPhA

## 5 Principle

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*N-nitrosamines* and *N-nitrosatable substances* migrate into a test solution. *N-nitrosatable substances* are converted to *N-nitrosamines* by acidification. The final test solutions are analysed for *N-nitrosamines* by a suitable validated analytical technique. The *N-nitrosamines* and *N-nitrosatable substances* are expressed in mg/kg of sample.

The test solution for *N-nitrosamines* in *finger paints* is water. The test solution for *N-nitrosatable substances* in *finger paints* and for *N-nitrosamines* and *N-nitrosatable substances* in *elastomers* is saliva test solution.

## 6 Reagents and apparatus

### 6.1 Reagents

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

**6.1.1 Sodium hydrogen carbonate (CAS 144-55-8)**

**6.1.2 Sodium chloride (CAS 7647-14-5)**

**6.1.3 Potassium carbonate (CAS 584-08-7)**

**6.1.4 Sodium nitrite (CAS 7632-00-0)**

**6.1.5 Hydrochloric acid (CAS 7647-01-0), aqueous solution, c(HCL) = 0,1 mol/l**

**6.1.6 Sodium hydroxide (CAS 1310-73-2), aqueous solution**,  $c(\text{NaOH}) = 0,1 \text{ mol/l}$

**6.1.7 Saliva test solution**

Dissolve  $(4,2 \pm 0,021) \text{ g}$  of the sodium hydrogen carbonate (6.1.1),  $(0,5 \pm 0,0025) \text{ g}$  of the sodium chloride (6.1.2),  $(0,2 \pm 0,0010) \text{ g}$  of the potassium carbonate (6.1.3) and  $(0,03 \pm 0,00015) \text{ g}$  of the sodium nitrite (6.1.4) in water and dilute to  $(950 \pm 5) \text{ ml}$  with water. Adjust to  $\text{pH } 9,0 \pm 0,1$  if necessary by adding the hydrochloric acid solution (6.1.5) or sodium hydroxide solution (6.1.6) drop by drop. Transfer into a 1 l volumetric flask and dilute to the mark with water.

This solution has a limited stability. Saliva test solution kept for more than five days shall not be used.

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

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

**6.1.10 Methanol**,  $\geq 99,9 \%$ , HPLC-grade.

**6.1.11 Formic acid**,  $\geq 99,5 \%$ , LC-MS grade.

**6.1.12 Eluent A**: 0,1 % (volume fraction) formic acid in water.

**6.1.13 Eluent B**: 0,1 % (volume fraction) formic acid in methanol.

**6.2 Standards**

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*N-nitrosamines* are degraded by ultraviolet light. Exposure of extracts or standards to sources such as sunlight or fluorescent tube light should be avoided. The standards shall be protected by wrapping in aluminium foil or using amber glassware and stored in the dark at a temperature of  $(5 \pm 3) ^\circ\text{C}$ .

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.

**6.2.1 *N-nitrosamines* or their solutions**, with known purities.

**6.2.2 Internal standard, d8-N-nitrosodiethanolamine (d8-NDELA)**, with known purity.

**6.2.3 Internal standard, d6-N-nitrosodimethylamine (d6-NDMA)**, with known purity.

**6.2.4 Stock solution of *N-nitrosamines***

Prepare a stock solution containing 10 mg/l of each *N-nitrosamine* (6.2.1) in methanol (6.1.10). This solution shall be stored in the absence of light at  $(-18 \pm 3) ^\circ\text{C}$ .

NOTE Certified *N-nitrosamines* standards can be purchased from several suppliers including storage and stability information.

**6.2.5 Solutions of internal standards**

**6.2.5.1 Stock solution of internal standards for elastomers**

Prepare a stock solution containing 1 mg/l d8-NDELA (6.2.2) and 1 mg/l d6-NDMA (6.2.3) in methanol (6.1.10). This solution shall be stored in the absence of light at  $(-18 \pm 3) ^\circ\text{C}$ .

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**6.2.5.2 Working solution of internal standards for finger paints**

Prepare an internal standard working solution containing 1 mg/l d8-NDELA (6.2.2) in water. This solution has a stability of one day.

**6.2.6 Calibration solutions****6.2.6.1 Calibration solutions for N-nitrosamines in finger paints**

Prepare five calibration solutions by diluting the stock solution of the *N-nitrosamines* (6.2.4) and the working solution of d8-NDELA (6.2.5.2) with water. The concentrations of the calibration solutions shall be 0,001 mg/l, 0,002 mg/l, 0,005 mg/l, 0,010 mg/l and 0,020 mg/l. Each solution shall contain 0,010 mg/l of d8-NDELA. These solutions have a stability of one day.

**6.2.6.2 Calibration solutions for N-nitrosatable substances in finger paints**

Prepare at least five calibration solutions by diluting the stock solutions of the *N-nitrosamines* (6.2.4) with saliva test solution (6.1.7). The concentration range of the calibration solutions shall be 0,001 mg/l to 0,05 mg/l. To 1 ml of each solution, add 0,020 ml of the internal standards stock solution containing d8-NDELA and d6-NDMA (6.2.5.1). Shake to mix the solutions. These solutions have a stability of one day.

**6.2.6.3 Calibration solutions for elastomers**

Prepare at least five calibration solutions by diluting the stock solutions of the *N-nitrosamines* (6.2.4) with saliva test solution (6.1.7). The concentration range of the calibration solutions shall be 0,000 2 mg/l to 0,05 mg/l. To 1 ml of each solution, add 0,020 ml of the internal standards stock solution containing d8-NDELA and d6-NDMA (6.2.5.1). Shake to mix the solutions. These solutions have a stability of one day.

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**6.3 Apparatus**

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Laboratory equipment that can come into contact with the sample shall be free from *N-nitrosamines*.

Standard laboratory equipment and equipment appropriate for applying the test method shall be used. The following equipment could be used when applying the test method specified in this standard.

**6.3.1 Vortex mixer****6.3.2 Shaking machine****6.3.3 Centrifuge**, capable of achieving not less than 20 000 *g***6.3.4 Glass balls****6.3.5 Conical flask**, made of amber glass**6.3.6 Oven**, capable of maintaining a temperature of (40 ± 2) °C**6.3.7 High performance liquid chromatography apparatus coupled with tandem mass spectrometry** equipped with atmospheric pressure ionization (APCI)