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

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Europastandarden EN 71-12:2016 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 71-12:2016.

Denna standard ersätter SS-EN 71-12:2013, utgåva 1.

The European Standard EN 71-12:2016 has the status of a Swedish Standard. This document contains the official English version of EN 71-12:2016.

This standard supersedes the Swedish Standard SS-EN 71-12:2013, edition 1.

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EUROPEAN STANDARD

EN 71-12

NORME EUROPÉENNE

EUROPÄISCHE NORM

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.

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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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SS-EN 71-12:2017 (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of an identical text or by endorsement, at the latest by June 2017, and conflicting national standards shall be withdrawn at the latest by June 2017.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.*

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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.

SS-EN 71-12:2017 (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.

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.