SLOVENSKI STANDARD
SIST EN 71-12:2013

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Varnost igrač - 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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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

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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of an identical text or by endorsement, at the latest by December 2013, and conflicting national standards shall be withdrawn at the latest by December 2013.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 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 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.

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

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 tested in *finger paint*. If there are indications of the presence of other *N-nitrosamines*, they should also be tested.

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* from toys intended for use by children under 36 months or in other toys or parts of toys intended to be placed into the mouth shall not exceed 0,05 mg/kg of toy material when tested in accordance with 7.3 and Clause 8, calculated as sum of all detected *N-nitrosamines* according to 9.2.

The migration of *N-nitrosatable substances* from toys intended for use by children under 36 months or in other toys or parts of toys intended to be placed into the mouth shall not exceed 1 mg/kg of toy material, calculated as sum of all detected *N-nitrosamines* after nitrosation.

At least the substances in Table 2 shall be tested in *elastomers*. If there are indications of the presence of other *N-nitrosamines* they should also be tested.

Table 2 — 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-nitrosodiethylamie	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	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

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.

N-nitrosamines are degraded by ultra-violet light. Exposure of extracts or standards to sources such as sunlight or fluorescent tube light should be avoided. The samples and standards shall be protected by wrapping in aluminium foil or using amber glassware and stored in the dark at a temperature of (5 ± 3) °C.

6.1.1 Sodium hydrogen carbonate.

6.1.2 Sodium chloride.

6.1.3 Potassium carbonate.

6.1.4 Sodium nitrite.

6.1.5 Hydrochloric acid solution, c(HCL) = 0,1 mol/l.

6.1.6 Sodium hydroxide solution, c(NaOH) = 0,1 mol/l.

6.1.7 Saliva test solution.

Dissolve 4,2 g of the sodium hydrogen carbonate (6.1.1), 0,5 g of the sodium chloride (6.1.2), 0,2 g of the potassium carbonate (6.1.3) and 30 mg of the sodium nitrite (6.1.4) in water and dilute to 900 ml with water. Adjust to pH 9,0 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.

The saliva test solution shall be prepared freshly every day to ensure an accurate nitrite concentration. If the solution is stored and not prepared freshly the laboratory shall prove that the nitrite concentration has not decreased during storage.

6.1.8 Hydrochloric acid solution, c(HCL) = 1 mol/l.

6.1.9 Sodium hydroxide solution, c(NaOH) = 1 mol/l.

6.1.10 Methanol, ≥ 99,9 %, HPLC-grade.

6.1.11 Formic acid, ≥ 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.