

Product specific toy standards

and a little bit more from EN71-series



Dr. Bertram Reindl
Bayerisches Landesamt für Gesundheit
und Lebensmittelsicherheit
Bavarian Health and Food Safety Authority
bertram.reindl@lgl.bayern.de

EN71- standards „Safety of Toys“

Directly product related

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 13	Olfactory board games, cosmetic kits and gustative games

Special material

Part 12	N-Nitrosamines and N-nitrosatable substances
---------	--

Product specific EN71- standards

- Very sensible area of these specific toys
- Emotional high ranking at consumer foreside
- Support for manufacturer
- Dedicated and very clear standards
- Strict age limits and adult supervision
- Positive lists of chemical substances, where necessary
- Exhaustive instructions for use and first aid
- Non design-restrictive: EC type examination stays open



1790



Foto: Deutsches Apotheken-Museum Heidelberg

Chemical toy

toy intended for the direct handling of chemical substances and mixtures and which is used in a manner appropriate to a given age-group and under the supervision of an adult

In particular:

chemistry sets, plastic embedding sets, miniature workshops for ceramics, enamelling or photography and similar toys which lead to a chemical reaction or similar substance alteration during use

Warnings (TSD, Annex V, Part B, No.4)

Chemical toys

The instructions for use include

- a warning of the dangerous nature of these substances or mixtures
- an indication of the precautions to be taken by the user in order to avoid hazards associated with them, which shall be specified concisely according to the type of toy.

The first aid - to be given in the event of serious accidents resulting from the use of this type of toy

Toys must be kept out of reach of children under a certain age, which shall be specified by the manufacturer.

Warning on packaging:

"Warning: Not suitable for children under (*) years. For use under adult supervision".

*

Age to be specified by the manufacturer.

EN71-4 Experimental sets for chemistry and related activities

Equipment

Containers and glassware

- Test tubes and other glassware
- Containers for reagents, substances and mixtures
- Packaging and closures
- Empty containers

Equipment for the transfer of liquid

Test tube stand and test tube holder

Eye protection

Marking

- individual containers, packaging and glassware
- primary packaging

Contents list with warnings and first aid information

Instructions for use

- advice for supervising adults
- safety rules

Chemical substances in

- Chemistry sets


- Crystal growing sets






- Carbon dioxide generating experimental sets



EN71-4: Table 4 — Maximum amounts of chemical substances for crystal growing sets and labelling

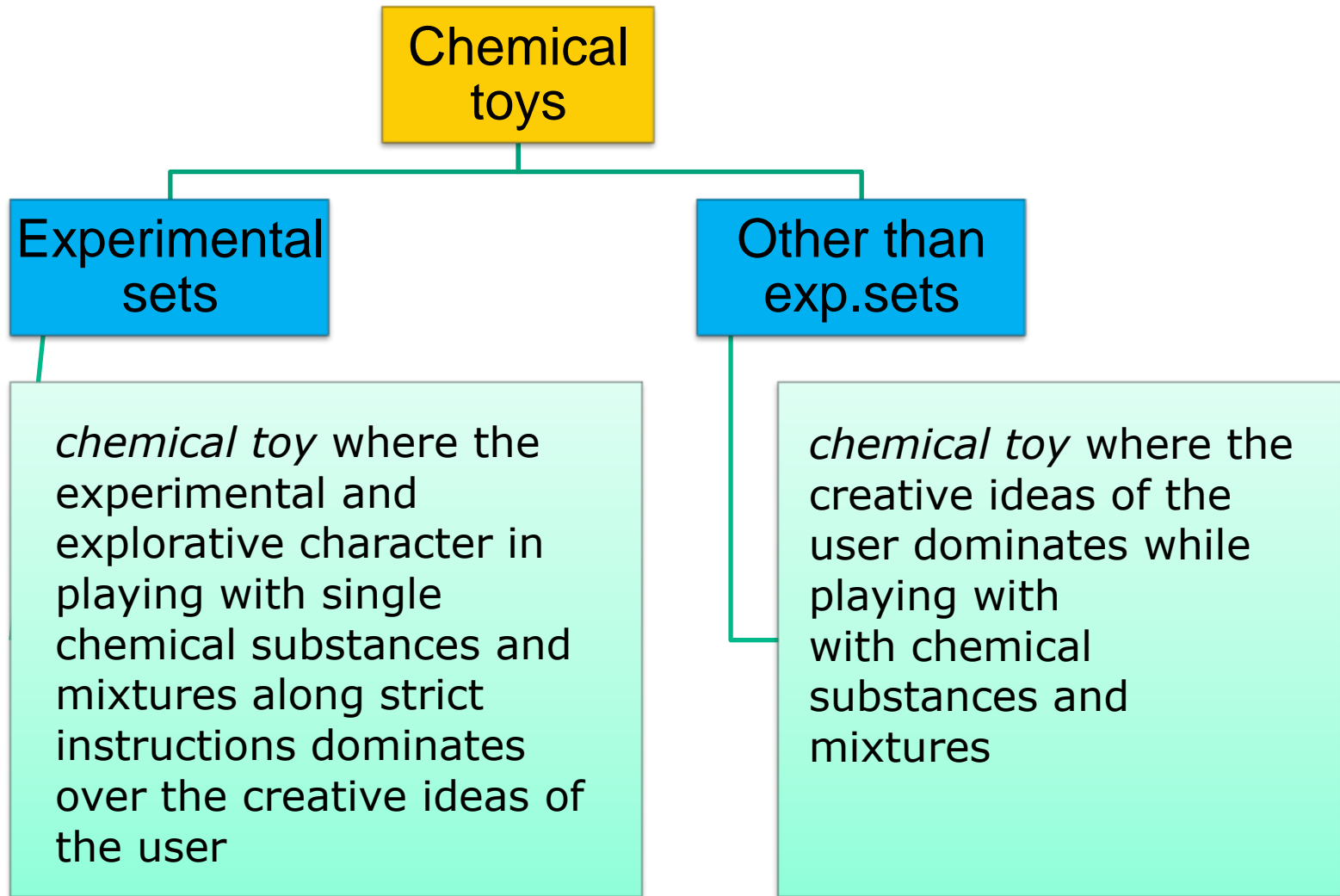
Chemical substances	Max. amount per set g	GHS Pictograms	Signal word
Ammonium chloride	30	GHS07 	Warning
Ammonium dihydrogen orthophosphate	600	-	-
Aluminium potassium sulfate	600	-	-
.... and 16 substances more			

EN71-4 Table 5 Maximum amounts of chemical substances for carbon dioxide generating experimental sets and labelling

Chemical substances	Max. amount per set g	GHS Pictogram	Signal word
Citric acid	100	GHS07 	Warning
Disodium hydrogen phosphate	20	–	–
Malic acid	60	GHS 07 	Warning
Potassium hydrogen carbonate	50	–	–
Potassium dihydrogen phosphate	100	–	–
Sodium dihydrogen phosphate	70	–	–
Tartaric acid	60	GHS07 	Warning

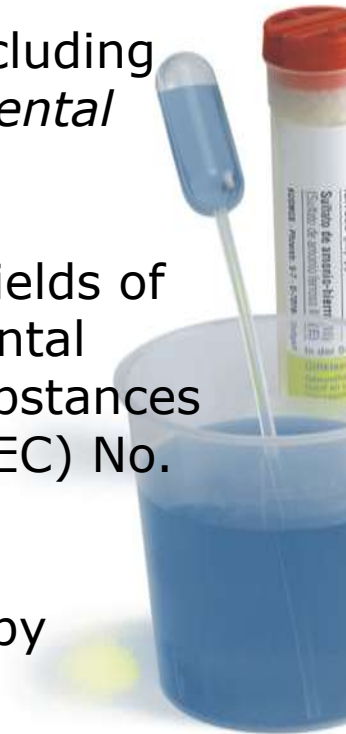
NOTE The maximum amounts specified in Table 5 refer to anhydrous chemicals. Equivalent amounts of the hydrated chemicals may replace the anhydrous substances.

Classification (EN71-4 and EN71-5)



Scope of EN71-4

- *experimental sets for chemistry and related activities including crystal growing sets, carbon dioxide generating experimental sets and supplementary sets*
- It also covers sets for chemical experiments within the fields of mineralogy, biology, physics, microscopy and environmental science whenever they contain one or more chemical substances and/or classified as hazardous according to Regulation (EC) No. 1272/2008/EC.
- This standard does not apply to toys which are covered by EN 71-13 (e.g. cosmetic kits).



Scope of EN71-5

- Plaster of Paris (gypsum) moulding sets
- Ceramic and vitreous enamelling materials supplied in miniature workshop sets
- Oven hardening plasticized PVC modelling clay sets
- Plastic moulding sets
 - Polystyrene granules
 - Embedding sets
- ~~Photographic processing sets~~
- Adhesives, paints, lacquers, varnishes, thinners and cleaning agents (solvents) supplied or recommended in model sets
 - Adhesives
 - Water-based paints and lacquers
 - Solvent-based paints, lacquers, thinners and cleaning solvents

EN71-5

Chemical toy (sets) without experimental sets

Modifications:

- Adaptation of substances to Regulation (EC) No. 1272/2008/EC and REACH
- (Adaptations for mixtures will follow in a coming revision for 2015)
- Almost adaptations on Marking, Warnings acc. to TSD



EN71-7: Finger paints Modifications ahead

- Colourants
- Preservatives
- Limits for impurities
 - Limits for primary aromatic amines
 - Limits for other impurities
- Taste and smell
- pH-value
- Binding agents, extenders, humectants and surfactants
- N-Nitrosamines

- Marking

- Methods
 - Validation of prim aromatic amines methods
 - New method for the determination of hexachlorobenzene, polychlorinated biphenyls and benzo[*a*]pyrene



Colourants (EN71-7)

Only *colourants* and colouring materials which are not fulfilling the criteria of any of the following hazard classes

- “acute toxicity” (hazard class 3.1),
- “Skin corrosion/irritation” (hazard class 3.2),
- “Serious eye damage/eye irritation” (hazard class 3.3),
- “Respiratory or skin sensitisation” (hazard class 3.4),
- “Germ cell mutagenicity” (hazard class 3.5),
- “Carcinogenicity” (hazard class 3.6),
- “Reproductive toxicity – adverse effects on sexual function and fertility or on development” (hazard class 3.7),
- “Specific target organ toxicity – single exposure effects other than narcotic effects” (hazard class 3.8),
- “Specific target organ toxicity – repeated exposure” (hazard class 3.9),
- “Aspiration hazard” (hazard class 3.10),

shall be used in *finger paints*.

Preservatives (EN71-7)

Preservation protects products in the long term against growth of bacteria, fungi and yeasts in water-based paint systems.

Positive list of preservatives (normative):

e.g.

- Bronopol
- Benzalkonium chloride
- Mixture of 5-chloro-2-methyl-isothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one with magnesium chloride and magnesium nitrate^a

EN71-7: limits of other impurities

Impurity	Limit (mg/kg)	Finger paints of concern
Polychlorinated biphenyls	2	<i>Finger paints</i> containing <i>colourant</i> products containing chlorine or manufactured in chlorinated solvents
Hexachlorobenzene	5	<i>Finger paints</i> containing <i>colourant</i> products containing chlorine or manufactured in chlorinated solvents
Benzo (a) pyrene	0,02	Only for <i>finger paints</i> containing carbon black

EN71-13 Olfactory board games, gustative board games, cosmetic kits and gustative kits

olfactory board game: toy the purpose of which is to assist a child to learn to recognise different odours or flavours

cosmetic kit: toy the purpose of which is to assist a child to learn to make products such as fragrances, soaps, creams, shampoos, bath foams, glosses, lipsticks, other make-up, tooth-paste and conditioners. The purpose of the kits is to mix ingredients to make cosmetic products without any chemical reaction during the mixing.

gustative games: toy the purpose of which is to allow children to make sweets or dishes which involve the use of food ingredients such as sweets, liquids, powders and aromas

~~**gustative board game:** toy the purpose of which is for a child to recognise and learn different tastes or flavours~~

supplementary set: incomplete *olfactory board game*, *cosmetic kit*, *gustative kit* or *gustative board game* which is intended to be used with a complete game or kit

EN71-13 Olfactory board games, cosmetic kits and gustative kits

Exemptions for these toys:

→ may contain certain of the allergenic fragrances, if the following conditions are all met:

- clear labelling of those fragrances on the packaging: “contains fragrances that may cause allergies”
- The resulting products that the child has made in accordance with the instructions comply with the requirements of Cosmetics directive if applicable.
- The fragrances comply with the relevant legislation on food, if applicable.

Such categories of products must not be permitted to be used by children under 36 months.

Allergenic fragrances exempted for EN71-13

(41)	Amyl cinnamal	122-40-7
(42)	Amylcinnamyl alcohol	101-85-9
(43)	Benzyl alcohol	100-51-6
(44)	Benzyl salicylate	118-58-1
(45)	Cinnamyl alcohol	104-54-1
(46)	Cinnamal	104-55-2
(47)	Citral	5392-40-5
(48)	Coumarin	91-64-5
(49)	Eugenol	97-53-0
(50)	Geraniol	106-24-1
(51)	Hydroxy-citronellal	107-75-5
(52)	Hydroxy-methylpentylcyclohexenecarboxaldehyde	31906-04-4
(53)	Isoeugenol	97-54-1
(54)	Oakmoss extracts	90028-68-5
(55)	Tree moss extracts	90028-67-4

EN71-13 Olfactory board games, cosmetic kits and gustative games

Modifications decided in week 42

EN71-12: N-Nitrosamines und N-nitrosatable substances

restricted in

- toys intended for use by children under 36 months or
- in other toys and parts of toys intended to be placed in the mouth
-
- Elastomers
 - Migration-limit:
 - 0,05 mg/kg N-nitrosamines
 - 1 mg/kg N-nitrosatable substances
- Finger paints
 - Migration-limit:
 - 0,02 mg/kg N-nitrosamines
 - 1 mg/kg N-nitrosatable substances

Definitions (EN71-12)

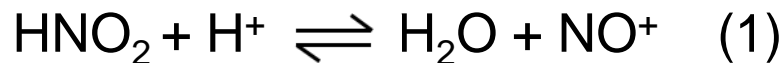
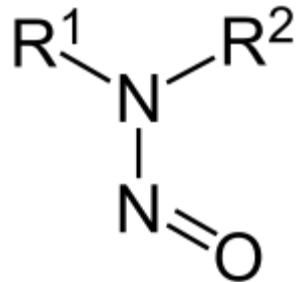
finger paint

paste and/or jelly like, coloured mixture specially designed for children to apply directly to suitable surfaces with the fingers and hands

elastomer

material which undergoes substantial, elastic ((fully) reversible) deformation when put under stress and consisting of three-dimensional networks of cross-linked flexible polymers

N-Nitrosamines and N-nitrosatable substances



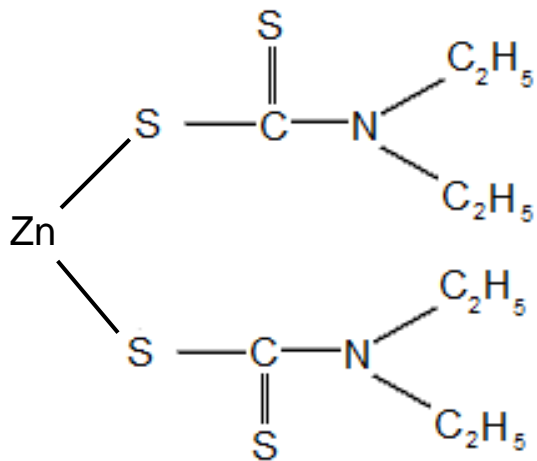
N-nitrosamine

substance characterized by the -N-N=O functional group, usually formed by the reaction of an amine (primarily a secondary amine) with a nitrosating agent, e.g. nitrite, at acidic pH

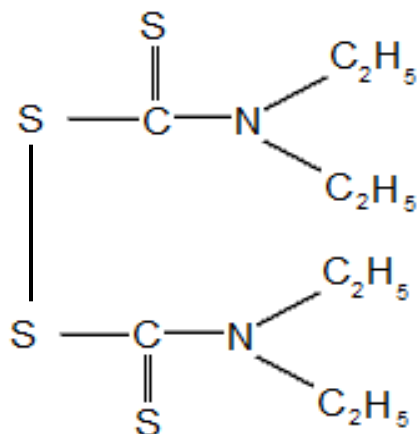
N-nitrosatable substance

substance which when released into the test solution undergoes nitrosation to form a *N-nitrosamine* under specified conditions

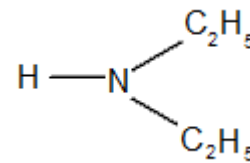
Examples for development of N-nitrosoamines



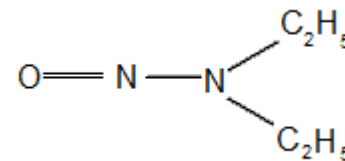
Zink-dialkyl-dithiocarbamate



Tetraalkyl-thiuramdisulfid



Dialkylamine



N-Nitrosodialkylamine

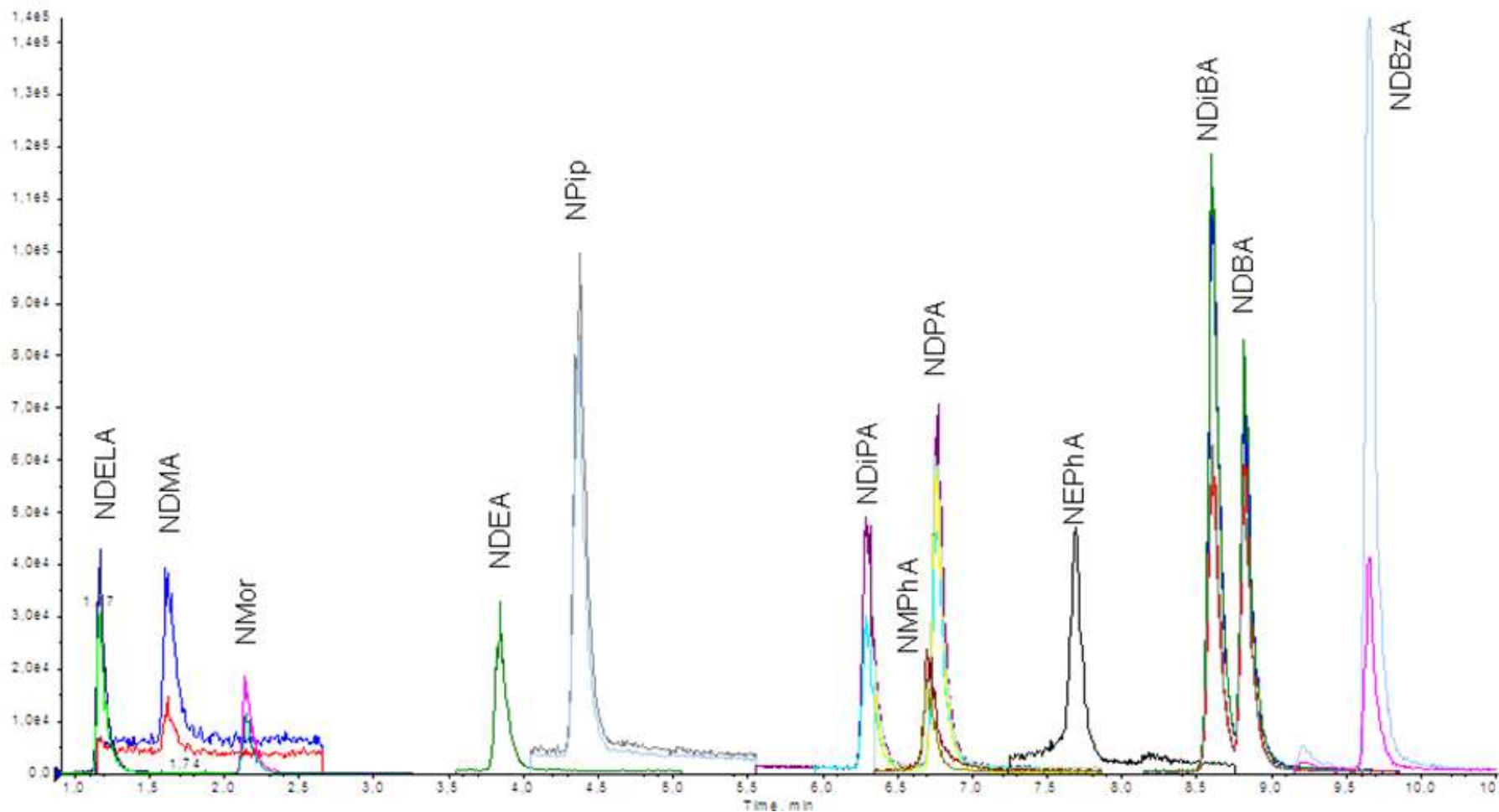
Precursors for N-nitrosamines in rubber (examples)

Accelerators:	CAS	resulting N-Nitrosamine
<i>Dithiocarbamates</i>		
Zinc dimethyl dithiocarbamate	137-30-4	NDMA
Zinc diethyl dithiocarbamate	14324-55-1	NDEA
Zinc dibenzyl dithiocarbamate	14726-36-4	NDBzA
Piperidine pentamethylene dithiocarbamate	98-77-1	NPIP
<i>Sulphenamides</i>		
N-Morpholinyl-2-benzothiazole sulfenamide	102-77-2	NMOR
<i>Thiuram sulphides</i>		
Tetramethylthiuram disulfide	137-26-8	NDMA
<i>Others</i>		
4,4'-Dithiodimorpholine	103-34-4	NMOR

List of N-Nitrosamines from EN71-12

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	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

Exemplary LC-MS/MS chromatogram



EN71- standards „Safety of Toys“: **New versions 2013**

Directly product related

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 13	Olfactory board games, gustative board games, cosmetic kits and gustative kits

Special materials

Part 12	N-Nitrosamines and n-nitrosatable substances
---------	--

**Chemical requirements
2013-07-20**

