

EU TOY DIRECTIVE 2009/48/EC: CHEMICAL REQUIREMENTS (IMPLEMENTATION 20 JULY 2013) - OVERVIEW

1. CARCINOGENS, MUTAGENS AND TOXIC FOR REPRODUCTION (CMRs)

CMRs, chemical substances or mixtures that may present diverse harmful effects for human health, are prohibited for use in toys.

CMRs can be defined as follows:

- Carcinogens (C): substances that cause or tend to cause cancer
- Mutagen (M): chemical or physical agent that induces permanent, transmissible genetic change
- Toxic for Reproduction (R): substances that may damage reproductive capacities or functions

Derogations:

- Within concentration limits in Dangerous Preparations Directive 1999/45/EC (DPD) or Regulation (EC) 1272/2008 on the Classification, Labelling and Packaging of substances and mixtures (CLP)
- Inaccessible for children (including inhalation)
- Evaluated and accepted by Scientific Committee: nickel in stainless steel is accepted, other applications can be submitted for assessment by the Scientific Committee

2. NITROSAMINES & NITROSATABLE SUBSTANCES

N-nitrosamines and N-nitrosatable substances are banned in toys for children under 36 months and in toys intended to be placed in the mouth unless the migration levels are:

- No more than 0.05 mg/kg for N-nitrosamines
- No more than 1 mg/kg for N-nitrosatable substances

List of N-nitrosamines:

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

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3. MIGRATION OF CERTAIN ELEMENTS

The EU Toy Safety Directive includes new restrictions on toxic elements. In total 19 elements (8 elements in old toy directive) are restricted and depending on the toy material category, different limits are applied (see page 4).

3 types of material are distinguished:

- Dry, brittle, powder-like or pliable,
- Liquid or sticky, and
- Scraped off toy material

4. ALLERGENIC FRAGRANCES














55 listed allergenic fragrances may not be used in toys, only technically unavoidable traces are allowed up to 100 mg/kg.

Additional 11 fragrance substances shall be listed on the toy, on affixed label, on the packaging or in an accompanying leaflet if concentration exceeds 100 mg/kg.

EU TOY DIRECTIVE 2009/48/EC:

CHEMICAL REQUIREMENTS (IMPLEMENTATION 20 JULY 2013) - FOCUS ON MIGRATION OF CERTAIN ELEMENTS (EN 71-3:2013)

The EU Toy Directive sets migration limits for 19 elements including now requirements for chromium (III) and chromium (VI) as well as requirements for tin and organic tin. Further details about the 3 distinct toy material categories are given below:

TOY MATERIAL CATEGORY		MATERIAL EXAMPLES	
CATEGORY 1 Solid toy material from which powder-like material is released during play	Dry	Compressed paint tablets	
	Brittle	Chalk, Crayons	
	Powder-like	Plaster of Paris	
	Pliable	Magic sand, Modelling compounds, Plastacine, Oven hardened PVC modelling compounds, Bouncing putty	
CATEGORY 2 Fluid or viscous toy material which can be ingested and/or to which dermal exposure occurs during play	Liquid	Bubble solution, Poster paints, Finger paints	
	Sticky	Liquid adhesives, Glue sticks, Slimes	
CATEGORY 3 Fluid or viscous toy material which can be ingested and/or to which dermal exposure occurs during play <i>(Most toy materials are of category 3)</i>	Surface Coatings	Paints, Varnishes, Electroplating, Vacuum deposited metals	
	Hard Polymers & Soft Polymers	-Polystyrene, ABS, uPVC, Polypropylene -Rubber, PVC, Elastomers, Leatherette	
	Wood	Fibreboards, Chipboards, Plywood	
	Textiles	Fuzzy felts, Cotton wool, Polyester staple fibres, Plush fabrics	
	Glass / Ceramics	Marbles, Fibre glass	
	Metals and Alloys	Steel, Nickel-silver	
	Other Materials	Foam, Leather, Bone, Natural sponge	

EU TOY DIRECTIVE 2009/48/EC:

CHEMICAL REQUIREMENTS (IMPLEMENTATION 20 JULY 2013) -
FOCUS ON MIGRATION OF CERTAIN ELEMENTS (EN 71-3:2013)

ELEMENT	EN 71-3:2013 (2009/48/EC)			PREVIOUS LIMITS	
	mg/kg in dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material	mg/kg in scraped off toy material	mg/kg toy material	mg/kg modelling clay
Aluminium *	5,625	1,406	70,000	–	–
Antimony	45	11.3	560	60	60
Arsenic	3.8	0.9	47	25	25
Barium **	1,500	375	18,750	1,000	250
Boron *	1,200	300	15,000	–	–
Cadmium	1.3	0.3	17	75	50
Chromium (III) *	37.5	9.4	460	60	25
Chromium (VI) *	0.02	0.005	0.2	(total)	(total)
Cobalt *	10.5	2.6	130	–	–
Copper *	622.5	156	7,700	–	–
Lead	13.5	3.4	160	90	90
Manganese *	1,200	300	15,000	–	–
Mercury	7.5	1.9	94	60	25
Nickel *	75	18.8	930	–	–
Selenium	37.5	9.4	460	500	500
Strontium *	4,500	1,125	56,000	–	–
Tin *	15,000	3,750	180,000	–	–
Organic Tin *	0.9	0.2	12	–	–
Zinc *	3,750	938	46,000	–	–

Notes: * New elements under the Toy Safety Directive 2009/48/EC effective 20 July 2013

** Barium: New limits proposed (Document No. COM/2012/002) have been adopted by the EN 71-3:2013

Cadmium: Lower soluble limits (Directive 2012/7/EU published on 2 March 2012 in the OJEU)

EU TOY DIRECTIVE 2009/48/EC:

CHEMICAL REQUIREMENTS (IMPLEMENTATION 20 JULY 2013) - FOCUS ON ALLERGENIC FRAGRANCES

55 listed allergenic fragrances may not be used in toys, only technically unavoidable traces are allowed up to 100 mg/kg.

NO.	NAME OF THE ALLERGENIC FRAGRANCE	CAS NUMBER
(1)	Alanroot oil (Inula helenium)	97676-35-2
(2)	Allylisothiocyanate	57-06-7
(3)	Benzyl cyanide	140-29-4
(4)	4 tert Butylphenol	98-54-4
(5)	Chenopodium oil	8006-99-3
(6)	Cyclamen alcohol	4756-19-8
(7)	Diethyl maleate	141-05-9
(8)	Dihydrocoumarin	119-84-6
(9)	2,4-Dihydroxy-3-methylbenzaldehyde	6248-20-0
(10)	3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)	40607-48-5
(11)	4,6-Dimethyl-8-tert-butylcoumarin	17874-34-9
(12)	Dimethyl citraconate	617-54-9
(13)	7,11-Dimethyl-4,6,10-dodecatrien-3-one	26651-96-7
(14)	6,10-Dimethyl-3,5,9-undecatrien-2-one	141-10-6
(15)	Diphenylamine	122-39-4
(16)	Ethyl acrylate	140-88-5
(17)	Fig leaf, fresh and preparations	68916-52-9
(18)	trans-2-Heptenal	18829-55-5
(19)	trans-2- Hexenal diethyl acetal	67746-30-9
(20)	trans-2- Hexenal dimethyl acetal	18318-83-7
(21)	Hydroabietyl alcohol	13393-93-6
(22)	4-Ethoxy-phenol	622-62-8
(23)	6-Isopropyl-2-decahydronaphthalenol	34131-99-2
(24)	7-Methoxycoumarin	531-59-9
(25)	4-Methoxyphenol 150	150-76-5
(26)	4-(p-Methoxyphenyl)-3-butene-2-one	943-88-4

NO.	NAME OF THE ALLERGENIC FRAGRANCE	CAS NUMBER
(27)	1-(p-Methoxyphenyl)-1-penten-3-one	104-27-8
(28)	Methyl trans-2-butenolate	623-43-8
(29)	6-Methylcoumarin	92-48-8
(30)	7-Methylcoumarin 2445	2445-83-2
(31)	5-Methyl-2,3-hexanedione	13706-86-0
(32)	Costus root oil (Saussurea lappa Clarke) 8023	8023-88-9
(33)	7-Ethoxy-4-methylcoumarin	87-05-8
(34)	Hexahydrocoumarin 700	700-82-3
(35)	Peru balsam, crude (Exudation of Myroxylon pereirae (Royle) Klotzsch)	8007-00-9
(36)	2-Pentylidene-cyclohexanone	25677-40-1
(37)	3,6,10-Trimethyl-3,5,9-undecatrien-2-one	1117-41-5
(38)	Verbena oil (Lippia citriodora Kunth)	8024-12-2
(39)	Musk ambrette (4-tert-Butyl-3-methoxy-2,6-dinitrotoluene)	83-66-9
(40)	4-Phenyl-3-buten-2-one	122-57-6
(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)	Treemoss extracts	90028-67-4

Additional 11 fragrance substances shall be listed on the toy, on affixed label, on the packaging or in an accompanying leaflet if concentration exceeds 100 mg/kg.

NO.	NAME OF THE ALLERGENIC FRAGRANCE	CAS NUMBER
(1)	Anisyl alcohol	105-13-5
(2)	Benzyl benzoate	120-51-4
(3)	Benzyl cinnamate	103-41-3
(4)	Citronellol	106-22-9
(5)	Farnesol	4602-84-0
(6)	Hexyl cinnamaldehyde	101-86-0
(7)	Lilial	80-54-6
(8)	d-Limonene	5989-27-5
(9)	Linalool	78-70-6
(10)	Methyl heptine carbonate	111-12-6
(11)	3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	127-51-5

CONTACT

For any questions, you can email us at consumer.products@sgs.com

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WHEN YOU NEED TO BE SURE

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