

Directive 2009/48/EC of the European Parliament and of the Council  
of 18 June 2009 on the safety of toys (Text with EEA relevance)

## ANNEX I

**List of products that, in particular, are not considered  
as toys within the meaning of this Directive**  
(as referred to in Article 2(1))

1. Decorative objects for festivities and celebrations
2. Products for collectors, provided that the product or its packaging bears a visible and legible indication that it is intended for collectors of 14 years of age and above. Examples of this category are:
  - (a) detailed and faithful scale models;
  - (b) kits for the assembly of detailed scale models;
  - (c) folk dolls and decorative dolls and other similar articles;
  - (d) historical replicas of toys; and
  - (e) reproductions of real fire arms.
3. Sports equipment, including roller skates, inline skates, and skateboards intended for children with a body mass of more than 20 kg
4. Bicycles with a maximum saddle height of more than 435 mm, measured as the vertical distance from the ground to the top of the seat surface, with the seat in a horizontal position and with the seat pillar set to the minimum insertion mark
5. Scooters and other means of transport designed for sport or which are intended to be used for travel on public roads or public pathways
6. Electrically driven vehicles which are intended to be used for travel on public roads, public pathways, or the pavement thereof
7. Aquatic equipment intended to be used in deep water, and swimming learning devices for children, such as swim seats and swimming aids
8. Puzzles with more than 500 pieces
9. Guns and pistols using compressed gas, with the exception of water guns and water pistols, and bows for archery over 120 cm long
10. Fireworks, including percussion caps which are not specifically designed for toys
11. Products and games using sharp-pointed missiles, such as sets of darts with metallic points
12. Functional educational products, such as electric ovens, irons or other functional products operated at a nominal voltage exceeding 24 volts which are sold exclusively for teaching purposes under adult supervision
13. Products intended for use for educational purposes in schools and other pedagogical contexts under the surveillance of an adult instructor, such as science equipment
14. Electronic equipment, such as personal computers and game consoles, used to access interactive software and their associated peripherals, unless the electronic equipment or the associated peripherals are specifically designed for and targeted at children and

- have a play value on their own, such as specially designed personal computers, key boards, joy sticks or steering wheels
15. Interactive software, intended for leisure and entertainment, such as computer games, and their storage media, such as CDs
  16. Babies' soothers
  17. Child-appealing luminaires
  18. Electrical transformers for toys
  19. Fashion accessories for children which are not for use in play

## ANNEX II

### PARTICULAR SAFETY REQUIREMENTS

#### I. Physical and Mechanical Properties

1. Toys and their parts and, in the case of fixed toys, their anchorages, must have the requisite mechanical strength and, where appropriate, stability to withstand the stresses to which they are subjected during use without breaking or becoming liable to distortion at the risk of causing physical injury.
2. Accessible edges, protrusions, cords, cables and fastenings on toys must be designed and manufactured in such a way that the risks of physical injury from contact with them are reduced as far as possible.
3. Toys must be designed and manufactured in such a way as not to present any risk or only the minimum risk inherent to their use which could be caused by the movement of their parts.
4.
  - (a) Toys and their parts must not present a risk of strangulation.
  - (b) Toys and their parts must not present a risk of asphyxiation by closing off the flow of air as a result of airway obstruction external to the mouth and nose.
  - (c) Toys and their parts must be of such dimensions as to not present a risk of asphyxiation by closing off the flow of air as a result of internal airway obstruction by objects wedged in the mouth or pharynx or lodged over the entrance to the lower airways.
  - (d) Toys, which are clearly intended for use by children under 36 months, and their component parts and any of their detachable parts must be of such dimensions as to prevent their being swallowed or inhaled. This also applies to other toys which are intended to be put in the mouth, and to their component parts and any of their detachable parts.
  - (e) The packaging in which toys are contained for retail sale must not present a risk of strangulation or asphyxiation caused by airway obstruction external to the mouth and nose.
  - (f) Toys contained within food or co-mingled with food must have their own packaging. This packaging, as it is supplied, must be of such dimensions as to prevent its being swallowed and/or inhaled.

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- (g) Toy packaging, as referred to in points (e) and (f), which is spherical, egg-shaped or ellipsoidal, and any detachable parts of this or of cylindrical toy packaging with rounded ends, must be of such dimensions as to prevent it from causing airway obstruction by being wedged in the mouth or pharynx or lodged over the entrance to the lower airways.
- (h) Toys firmly attached to a food product at the moment of consumption, in such a way that the food product needs to be consumed in order to get direct access to the toy, shall be prohibited. Parts of toys otherwise directly attached to a food product shall fulfil the requirements set out in points (c) and (d).
- 5. Aquatic toys must be designed and manufactured so as to reduce as far as possible, taking into account the recommended use of the toy, any risk of loss of buoyancy of the toy and loss of support afforded to the child.
- 6. Toys which it is possible to get inside and which thereby constitute an enclosed space for occupants must have a means of exit which the intended user can open easily from the inside.
- 7. Toys conferring mobility on their users must, as far as possible, incorporate a braking system which is suited to the type of toy and is commensurate with the kinetic energy generated by it. Such a system must be easy for the user to operate without risk of ejection or physical injury for the user or for third parties.

The maximum design speed of electrically driven ride-on toys must be limited so as to minimise the risk of injury.

- 8. The form and composition of projectiles and the kinetic energy they may generate when fired from a toy designed for that purpose must be such that, taking into account the nature of the toy, there is no risk of physical injury to the user or to third parties.
- 9. Toys must be manufactured so as to ensure that:
  - (a) the maximum and minimum temperature of any accessible surfaces does not cause injury when touched; and
  - (b) liquids and gases contained within the toy do not reach temperatures or pressures which are such that their escape from the toy, other than for reasons essential to the proper functioning of the toy, might cause burns, scalds or other physical injury.
- 10. Toys which are designed to emit a sound shall be designed and manufactured in such a way in terms of the maximum values for impulse noise and continuous noise that the sound from them is not able to impair children's hearing.
- 11. Activity toys shall be manufactured so as to reduce the risk of crushing or trapping of body parts or trapping of clothing and of falls, impacts and drowning as far as possible. In particular, any surface of such a toy accessible for one or more children to play on shall be designed to bear their load.

## II. **Flammability**

- 1. Toys must not constitute a dangerous flammable element in the child's environment. They must therefore be composed of materials which fulfil one or more of the following conditions:
  - (a) they do not burn if directly exposed to a flame or spark or other potential source of fire;
  - (b) they are not readily flammable (the flame goes out as soon as the fire cause disappears);

- (c) if they do ignite, they burn slowly and present a low rate of spread of the flame;
- (d) irrespective of the toy's chemical composition, they are designed so as to mechanically delay the combustion process.

Such combustible materials must not constitute a risk of ignition for other materials used in the toy.

2. Toys which, for reasons essential to their functioning, contain substances or mixtures that meet the classification criteria laid down in Section 1 of Appendix B, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, must not contain, as such, substances or mixtures which may become flammable due to the loss of non-flammable volatile components.
3. Toys other than toy percussion caps must not be explosive or contain elements or substances likely to explode when used as specified in the first subparagraph of Article 10(2).
4. Toys and, in particular, chemical games and toys, must not contain as such substances or mixtures:
  - (a) which, when mixed together, may explode through chemical reaction or through heating;
  - (b) which may explode when mixed with oxidizing substances; or
  - (c) which contain volatile components which are flammable in air and liable to form a flammable or explosive vapour/air mixture.

### III. Chemical Properties

1. Toys shall be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures of which the toys are composed or which they contain when the toys are used as specified in the first subparagraph of Article 10(2).

Toys shall comply with the relevant Community legislation relating to certain categories of products or to restrictions for certain substances and mixtures.

2. Toys that are themselves substances or mixtures must comply also with Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances<sup>(1)</sup>, Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations<sup>(2)</sup> and Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures<sup>(3)</sup>, as applicable, relating to the classification, packaging and labelling of certain substances and mixtures.
3. Without prejudice to the restrictions referred to in the second paragraph of point 1, substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys.

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4. By way of derogation from point 3, substances or mixtures classified as CMR of the categories laid down in Section 3 of Appendix B may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one or more of the following conditions is met:
- (a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;
  - (b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2);
  - (c) a decision in accordance with Article 46(3) has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A.

That decision may be taken if the following conditions are met:

- (i) the use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure;
- (ii) there are no suitable alternative substances or mixtures available, as documented in an analysis of alternatives; and
- (iii) the substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006.

The Commission shall mandate the relevant Scientific Committee to re-evaluate those substances or mixtures as soon as safety concerns arise and at the latest every five years from the date that a decision in accordance with Article 46(3) was taken.

5. By way of derogation from point 3, substances or mixtures classified as CMR of the categories laid down in Section 4 of Appendix B may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one of the following conditions is met:
- (a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;
  - (b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2); or
  - (c) a decision in accordance with Article 46(3) has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A.

That decision may be taken if the following conditions are met:

- (i) the use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure; and

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- (ii) the substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006.

The Commission shall mandate the relevant Scientific Committee to re-evaluate those substances or mixtures as soon as safety concerns arise and at the latest every five years from the date that a decision in accordance with Article 46(3) was taken.

6. Points 3, 4 and 5 shall not apply to nickel in stainless steel.
7. Points 3, 4 and 5 shall not apply to materials that comply with the specific limit values set out in Appendix C, or, until such provisions have been laid down, but not later than 20 July 2017, to materials covered by and complying with the provisions for food contact materials set out in Regulation (EC) No 1935/2004 and the related specific measures for particular materials.
8. Without prejudice to the application of points 3 and 4, nitrosamines and nitrosable substances shall be prohibited for use in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth if the migration of the substances is equal to or higher than 0,05 mg/kg for nitrosamines and 1 mg/kg for nitrosable substances.
9. The Commission shall systematically and regularly evaluate the occurrence of hazardous substances of materials in toys. These evaluations shall take into account reports of market surveillance bodies and concerns expressed by Member States and stakeholders.
10. Cosmetic toys, such as play cosmetics for dolls, shall comply with the compositional and labelling requirements laid down in Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products<sup>(4)</sup>.
11. Toys shall not contain the following allergenic fragrances:

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

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(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	150-76-5
(26)	4-(p-Methoxyphenyl)-3-butene-2-one	943-88-4
(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	2445-83-2
(31)	5-Methyl-2,3-hexanedione	13706-86-0
(32)	Costus root oil (Saussurea lappa Clarke)	8023-88-9
(33)	7-Ethoxy-4-methylcoumarin	87-05-8
(34)	Hexahydrocoumarin	700-82-3
(35)	Peru balsam, crude (Exudation of Myroxylon pereirae (Royle) Klotzsch)	8007-00-9
(36)	2-Pentylidene-cyclohexanone	25677-40-1



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(37)	3,6,10-Trimethyl-3,5,9-undecatrien-2-one	1117-41-5
(38)	Verbena oil ( <i>Lippia citriodora</i> 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

However, the presence of traces of these fragrances shall be allowed provided that such presence is technically unavoidable under good manufacturing practice and does not exceed 100 mg/kg.

In addition, the names of the following allergenic fragrances shall be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, if added to a toy, as such, at concentrations exceeding 100 mg/kg in the toy or components thereof:

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

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(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

12. The use of the fragrances set out in points 41 to 55 of the list set out in the first paragraph of point 11 and of the fragrances set out in points 1 to 11 of the list set out in the third paragraph of that point shall be allowed in olfactory board games, cosmetic kits and gustative games, provided that:

- (i) those fragrances are clearly labelled on the packaging, and the packaging contains the warning set out in point 10 of Part B of Annex V;
- (ii) if applicable, the resulting products made by the child in accordance with the instructions comply with the requirements of Directive 76/768/EEC; and
- (iii) if applicable, those fragrances comply with the relevant legislation on food.

Such olfactory board games, cosmetic kits and gustative games shall not be used by children under 36 months and shall comply with point 1 of Part B of Annex V.

13. Without prejudice to points 3, 4 and 5, the following migration limits, from toys or components of toys, shall not be exceeded:

<b>Element</b>	<b>mg/kg in dry, brittle, powder-like or pliable toy material</b>	<b>mg/kg in liquid or sticky toy material</b>	<b>mg/kg in scraped-off toy material</b>
Aluminium	5 625	1 406	70 000
Antimony	45	11,3	560
Arsenic	3,8	0,9	47
[ <sup>F1</sup> Barium]	1 500	375	18 750]
Boron	1 200	300	15 000
[ <sup>F2</sup> Cadmium]	1,3	0,3	17]
Chromium (III)	37,5	9,4	460
[ <sup>F3</sup> Chromium (VI)]	0,02	0,005	0,053]
Cobalt	10,5	2,6	130
Copper	622,5	156	7 700
[ <sup>F4</sup> Lead]	2,0	0,5	23]

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Manganese	1 200	300	15 000
Mercury	7,5	1,9	94
Nickel	75	18,8	930
Selenium	37,5	9,4	460
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

#### Textual Amendments

- F1** Substituted by Commission Regulation (EU) No 681/2013 of 17 July 2013 amending part III of Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys (Text with EEA relevance).
- F2** Substituted by Commission Directive 2012/7/EU of 2 March 2012 amending, for the purpose of adaptation to technical progress, part III of Annex II to Directive 2009/48/EC of the European Parliament and of the Council relating to toy safety (Text with EEA relevance).
- F3** Substituted by Commission Directive (EU) 2018/725 of 16 May 2018 amending, for the purpose of adaptation to technical and scientific developments, point 13 of part III of Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards chromium VI.
- F4** Substituted by Council Directive (EU) 2017/738 of 27 March 2017 amending, for the purpose of adapting to technical progress, Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards lead (Text with EEA relevance).

These limit values shall not apply to toys or components of toys which, due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin when used as specified in the first subparagraph of Article 10(2).

#### IV. Electrical Properties

1. Toys shall not be powered by electricity of a nominal voltage exceeding 24 volts direct current (DC) or the equivalent alternating current (AC) voltage, and their accessible parts shall not exceed 24 volts DC or the equivalent AC voltage.

Internal voltages shall not exceed 24 volts DC or the equivalent AC voltage unless it is ensured that the voltage and the current combination generated do not lead to any risk or harmful electric shock, even when the toy is broken.

2. Parts of toys which are connected to, or liable to come into contact with, a source of electricity capable of causing electric shock, together with the cables or other conductors through which electricity is conveyed to such parts, must be properly insulated and mechanically protected so as to prevent the risk of such shock.
3. Electric toys must be designed and manufactured in such a way as to ensure that the maximum temperatures reached by all directly accessible surfaces are not such as to cause burns when touched.
4. Under foreseeable fault conditions, toys must provide protection against electrical hazards arising from an electrical power source.

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5. Electric toys must provide adequate protection against fire hazards.
6. Electric toys must be designed and manufactured in such a way that electric, magnetic and electromagnetic fields and other radiations generated by the equipment are limited to the extent necessary for the operation of the toy, and must operate at a safe level in compliance with the generally acknowledged state of the art, taking account of specific Community measures.
7. Toys which have an electronic control system must be designed and manufactured in such a way that the toy operates safely even when the electronic system starts malfunctioning or fails due to failure of the system itself or an outside factor.
8. Toys must be designed and manufactured in such a way that they do not present any health hazards or risk of injury to eyes or skin from lasers, light-emitting diodes (LEDs) or any other type of radiation.
9. The electrical transformer of a toy shall not be an integral part of the toy.

#### V. **Hygiene**

1. Toys must be designed and manufactured in such a way as to meet hygiene and cleanliness requirements in order to avoid any risk of infection, sickness or contamination.
2. A toy intended for use by children under 36 months must be designed and manufactured in such a way that it can be cleaned. A textile toy shall, to this end, be washable, except if it contains a mechanism that may be damaged if soak washed. The toy shall fulfil the safety requirements also after having been cleaned in accordance with this point and the manufacturer's instructions.

#### VI. **Radioactivity**

Toys shall comply with all relevant measures adopted under Chapter III of the Treaty establishing the European Atomic Community.

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[<sup>F5</sup>Appendix ALIST OF CMR SUBSTANCES AND THEIR PERMITTED USES  
IN ACCORDANCE WITH POINTS 4, 5 AND 6 OF PART III

<b>Substance</b>	<b>Classification</b>	<b>Permitted use</b>
Nickel	CMR 2	In toys and toy components made of stainless steel. In toy components which are intended to conduct an electric current.]

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## Appendix B

### CLASSIFICATION OF SUBSTANCES AND MIXTURES

As a result of the timing of the application of Regulation (EC) No 1272/2008, there are equivalent ways of referring to a given classification that should be used at different points in time.

#### 1. **Criteria for classifying substances and mixtures for the purposes of point 2 of Part II**

A. Criteria to be applied from 20 July 2011 until 31 May 2015:

##### *Substances*

The substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

- (a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
- (b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
- (c) hazard class 4.1;
- (d) hazard class 5.1.

##### *Mixtures*

The mixture is dangerous within the meaning of Directive 67/548/EEC.

B. Criteria to be applied from 1 June 2015:

The substance or mixture fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

- (a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
- (b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
- (c) hazard class 4.1;
- (d) hazard class 5.1.

#### 2. **Community legal acts governing the use of certain substances for the purposes of points 4(a) and 5(a) of Part III**

From 20 July 2011 until 31 May 2015, the relevant concentrations for the classification of mixtures containing the substances shall be those established in accordance with Directive 1999/45/EC.

From 1 June 2015, the relevant concentrations for the classification of mixtures containing the substances shall be those established in accordance with Regulation (EC) No 1272/2008.

#### 3. **Categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of point 4 of Part III**

##### *Substances*

Point 4 of Part III concerns substances classified as CMR category 1A and 1B under Regulation (EC) No 1272/2008.

*Mixtures*

From 20 July 2011 until 31 May 2015, point 4 of Part III concerns mixtures classified as CMR category 1 and 2 under Directive 1999/45/EC and Directive 67/548/EEC as applicable.

From 1 June 2015, point 4 of Part III concerns mixtures classified as CMR category 1A and 1B under Regulation (EC) No 1272/2008.

**4. Categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of point 5 of Part III**

*Substances*

Point 5 of Part III concerns substances classified as CMR category 2 under Regulation (EC) No 1272/2008.

*Mixtures*

From 20 July 2011 until 31 May 2015, point 5 of Part III concerns mixtures classified as CMR category 3 under Directive 1999/45/EC and Directive 67/548/EEC as applicable.

From 1 June 2015, point 5 of Part III concerns mixtures classified as CMR category 2 under Regulation (EC) No 1272/2008.

**5. Categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of Article 46(3)**

*Substances*

Article 46(3) concerns substances classified as CMR category 1A, 1B and 2 under Regulation (EC) No 1272/2008.

*Mixtures*

From 20 July 2011 until 31 May 2015, Article 46(3) concerns mixtures classified as CMR category 1, 2, 1999 and 3 under Directive 1999/45/EC and Directive 67/548/EEC as applicable.

From 1 June 2015, Article 46(3) concerns mixtures classified as CMR category 1A, 1B and 2 under Regulation (EC) No 1272/2008.

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## [<sup>F6</sup>Appendix C

Specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth adopted in accordance with Article 46(2)

<b>Substance</b>	<b>CAS No</b>	<b>Limit value</b>
TCEP	115-96-8	5 mg/kg (content limit)
TCP	13674-84-5	5 mg/kg (content limit)
TDCP	13674-87-8	5 mg/kg (content limit)
[ <sup>F7</sup> Bisphenol A	80-05-7	0,04 mg/l (migration limit) in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005]
[ <sup>F8</sup> Formamide	75-12-7	20 µg/m <sup>3</sup> (emission limit) after a maximum of 28 days from commencement of the emission testing of foam toy materials containing more than 200 mg/kg (cut-off limit based on content)]
[ <sup>F9</sup> 1,2-benzisothiazol-3(2H)-one	2634-33-5	5 mg/kg (content limit) in aqueous toy materials, in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005]
[ <sup>F10</sup> Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	55965-84-9	1 mg/kg (content limit) in aqueous toy materials
5-Chloro-2-methyl-isothiazolin-3(2H)-one	26172-55-4	0,75 mg/kg (content limit) in aqueous toy materials
2-methylisothiazolin-3(2H)-one	2682-20-4	0,25 mg/kg (content limit) in aqueous toy materials]
[ <sup>F11</sup> Phenol	108-95-2	5 mg/l (migration limit) in polymeric materials in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005. 10 mg/kg (content limit) as a preservative in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005.]]



### ANNEX III

#### EC DECLARATION OF CONFORMITY

1. No ... (unique identification of the toy(s))
2. Name and address of the manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer:
4. Object of the declaration (identification of toy allowing traceability). It shall include a colour image of sufficient clarity to enable the identification of the toy.
5. The object of the declaration described in point 4 is in conformity with the relevant Community harmonisation legislation:
6. References to the relevant harmonised standards used, or references to the specifications in relation to which conformity is declared:
7. Where applicable: the notified body ... (name, number) ... performed ... (description of intervention) ... and issued the certificate:
8. Additional information:

Signed for and on behalf of:

(place and date of issue)

(name, function)(signature)

### ANNEX IV

#### TECHNICAL DOCUMENTATION

The technical documentation referred to in Article 21 shall contain, in particular, so far as relevant for assessment:

- (a) a detailed description of the design and manufacture, including a list of components and materials used in the toy as well as the safety data sheets on chemicals used, to be obtained from the chemical suppliers;
- (b) the safety assessment(s) carried out in accordance with Article 18;
- (c) a description of the conformity assessment procedure followed;
- (d) a copy of the EC declaration of conformity;
- (e) the addresses of the places of manufacture and storage;
- (f) copies of documents that the manufacturer has submitted to a notified body, if involved;
- (g) test reports and description of the means whereby the manufacturer ensured conformity of production with the harmonised standards, if the manufacturer followed the internal production control procedure referred to in Article 19(2); and

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- (h) a copy of the EC-type examination certificate, a description of the means whereby the manufacturer ensured conformity of the production with the product type as described in the EC-type examination certificate, and copies of the documents that the manufacturer submitted to the notified body, if the manufacturer submitted the toy to EC-type examination and followed the conformity to type procedure referred to in Article 19(3).

## ANNEX V

### WARNINGS

(as referred to in Article 11)

#### PART A

##### GENERAL WARNINGS

The user limitations referred to in Article 11(1) shall include at least the minimum or maximum age of the user and, where appropriate, the abilities of the user, the maximum or minimum weight of the user and the need to ensure that the toy is used only under adult supervision.

#### PART B

##### SPECIFIC WARNINGS AND INDICATIONS OF PRECAUTIONS TO BE TAKEN WHEN USING CERTAIN CATEGORIES OF TOYS

###### 1. Toys not intended for use by children under 36 months

Toys which might be dangerous for children under 36 months of age shall bear a warning such as 'Not suitable for children under 36 months' or 'Not suitable for children under three years' or a warning in the form of the following graphic:



These warnings shall be accompanied by a brief indication, which may appear in the instructions for use, of the specific hazard calling for this precaution.

This point shall not apply to toys which, on account of their function, dimensions, characteristics or properties, or on other cogent grounds, are manifestly unsuitable for children under 36 months.

###### 2. Activity toys

Activity toys shall bear the following warning:

Only for domestic use.

Activity toys attached to a crossbeam as well as other activity toys, where appropriate, shall be accompanied by instructions drawing attention to the need to carry out checks and maintenance of the main parts (suspensions, fixings, anchorages, etc.) at intervals, and pointing out that, if these checks are not carried out, the toy may cause a fall or overturn.

Instructions must also be given as to the correct assembly of the toy, indicating those parts which can present a danger if incorrectly assembled. Specific information regarding a suitable surface on which to place the toy shall be given.

### 3. **Functional toys**

Functional toys shall bear the following warning:

To be used under the direct supervision of an adult.

In addition, these toys shall be accompanied by directions giving working instructions as well as the precautions to be taken by the user, with the warning that failure to take these precautions will expose the user to the hazards – to be specified – normally associated with the appliance or product of which the toy is a scale model or imitation. It shall also be indicated that the toy must be kept out of the reach of children under a certain age, which shall be specified by the manufacturer.

### 4. **Chemical toys**

Without prejudice to the application of the provisions laid down in applicable Community legislation on the classification, packaging and labelling of certain substances or mixtures, the instructions for use of toys containing inherently dangerous substances or mixtures shall bear a warning of the dangerous nature of these substances or mixtures and 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 shall also be mentioned. It shall also be stated that the toy must be kept out of reach of children under a certain age, which shall be specified by the manufacturer.

In addition to the instructions provided for in the first subparagraph, chemical toys shall bear the following warning on their packaging:

Not suitable for children under<sup>(5)</sup> years. For use under adult supervision.

In particular, the following are regarded as chemical toys: 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.

### 5. **Skates, roller skates, online skates, skateboards, scooters and toy bicycles for children**

Where these toys are offered for sale as toys, they shall bear the following warning:

Protective equipment should be worn. Not to be used in traffic.

Moreover, the instructions for use shall contain a reminder that the toy must be used with caution, since it requires great skill, so as to avoid falls or collisions causing injury to the user or third parties. Some indication shall also be given as to recommended protective equipment (helmets, gloves, knee-pads, elbow-pads, etc.).

### 6. **Aquatic toys**

Aquatic toys shall bear the following warning:

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Only to be used in water in which the child is within its depth and under adult supervision.

7. **Toys in food**

Toys contained in food or co-mingled with food shall bear the following warning:

Toy inside. Adult supervision recommended.

8. **Imitations of protective masks and helmets**

Imitations of protective masks and helmets shall bear the following warning:

This toy does not provide protection.

9. **Toys intended to be strung across a cradle, cot or perambulator by means of strings, cords, elastics or straps**

Toys intended to be strung across a cradle, cot or perambulator by means of strings, cords, elastics or straps shall carry the following warning on the packaging, which shall also be permanently marked on the toy:

To prevent possible injury by entanglement, remove this toy when the child starts trying to get up on its hands and knees in a crawling position.

10. **Packaging for fragrances in olfactory board games, cosmetic kits and gustative games**

Packaging for fragrances in olfactory board games, cosmetic kits and gustative games that contain the fragrances set out in points 41 to 55 of the list set out in the first paragraph of point 11 of Part III of Annex II and of the fragrances set out in points 1 to 11 of the list set out in third paragraph of that point shall contain the following warning:

Contains fragrances that may cause allergies.

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- (1) OJ 196, 16.8.1967, p. 1.
- (2) OJ L 200, 30.7.1999, p. 1.
- (3) OJ L 353, 31.12.2008, p. 1.
- (4) OJ L 262, 27.9.1976, p. 169.
- (5) Age to be specified by the manufacturer.