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ANNEXES 1 to 8

**ANNEXES**

**to the**

**PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF  
THE COUNCIL**

**on the safety of toys and repealing Directive 2009/48/EC**

{SEC(2023) 297 final} - {SWD(2023) 268 final} - {SWD(2023) 269 final} -  
{SWD(2023) 270 final}

## ANNEX I

### **PRODUCTS TO WHICH THIS REGULATION DOES NOT APPLY**

#### **Part I – Toys excluded from the scope of this Regulation**

1. Playground equipment intended for public use;
2. automatic playing machines, whether coin operated or not, intended for public use;
3. toy vehicles equipped with combustion engines;
4. toy steam engines

#### **Part II- Products that are not considered as toys within the meaning of this Regulation**

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 and above. Examples of this category are:
  - (a) detailed 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 or 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;
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**

#### **Part I Physical and Mechanical Properties**

1. Toys and their parts and, in the case of fixed toys, their anchorages, shall 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 shall be designed and manufactured in such a way that the risks of physical injury from contact with them are reduced as much as possible.
3. Toys shall be designed and manufactured in such a way as not to present any risk to health and safety 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 shall not present a risk of strangulation.
  - (b) Toys and their parts shall 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 shall 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, shall be of such dimensions as to prevent them 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 shall 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 shall have their own packaging. This packaging, as it is supplied, must be of such dimensions as to prevent it from being swallowed and/or inhaled.
  - (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, shall 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 shall be designed and manufactured so as to reduce as much 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 shall have a means of exit which the intended user can open easily from the inside.
7. Toys conferring mobility on their users shall, 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 shall be easy for the user to operate without risk of ejection or physical injury for the user or for third parties.

For electrically driven ride-on toys, the maximum representative potential operating speed determined by the design of the toy shall 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 shall 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 shall be manufactured so as to ensure that:
  - (a) the maximum and minimum temperature of any accessible surfaces does not cause injury when touched;
  - (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 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 the risk of falls, impacts and drowning as much as possible. In particular, any surface of such a toy that is accessible for one or more children to play on shall be designed to bear their load.

## **Part II Flammability**

1. Toys shall not constitute a dangerous flammable element in the child's environment. They shall 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.

Combustible materials in the toy shall not constitute a risk of ignition for other materials used in the toy.

2. Toys meeting both conditions below shall not, as such, contain substances or mixtures which may become flammable due to the loss of non-flammable volatile components:
  - (a) toys which, for reasons essential to their functioning, contain substances or mixtures that meet the classification criteria of any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:
    - (1) hazard classes 2.1 to 2.4, 2.6 and 2.7, hazard class 2.8 types A and B;
    - (2) hazard classes 2.9, 2.10 and 2.12, hazard class 2.13 categories 1 and 2;
    - (3) hazard class 2.14, categories 1 and 2, hazard class 2.15 types A to F; hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development;
    - (4) hazard class 3.8 effects other than narcotic effects;
    - (5) hazard classes 3.9 and 3.10;
    - (6) hazard class 4.1;
    - (7) hazard class 5.1;
  - (b) and toys containing materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities.
3. Toys other than toy percussion caps shall not be explosive or contain elements or substances likely to explode when used as specified in Article 5(2), first subparagraph.
4. Toys and, in particular, chemical games and toys, shall 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.

### **Part 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 Article 5(2), first subparagraph.

Toys shall comply with the relevant Union legislation relating to certain categories of products or to restrictions for certain substances and mixtures. Toys or their parts and their packaging that can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use, shall also comply with Regulation (EC) No 1935/2004.
2. Toys that are themselves substances or mixtures shall comply also with Regulation (EC) No 1272/2008 .

3. Toys shall comply with the specific requirements and conditions for chemical substances set out in part A of the Appendix and with the labelling requirements set out in part B of the Appendix.
4. The use in toys, components of toys or micro-structurally distinct parts of toys, of substances or mixtures classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 in any of the following categories is prohibited:
  - (a) carcinogenicity, germ cell mutagenicity or reproductive toxicity (CMR) category 1A, 1B or 2;
  - (b) endocrine disruption category 1 or 2;
  - (c) specific target organ toxicity category 1, either in single exposure or in repeated exposure;
  - (d) respiratory sensitisation category 1.
5. The non-intended presence of a substance or mixture referred to in point 4 that stems from impurities of natural or synthetic ingredients, or from the manufacturing process and that is technically unavoidable in good manufacturing practice, shall be permitted provided that, despite such presence, toys remain in conformity with the general safety requirement.
6. By way of derogation from point 4, substances or mixtures prohibited under that point may be used in toys if they are listed in Part C of the Appendix, under the conditions specified therein.
7. Points 4 to 6 shall not apply to:
  - (a) materials that comply with the conditions set out for specific substances in Part A of the Appendix, as regards those substances;
  - (b) batteries in toys; or
  - (c) toy components necessary for electronic or electric functions of the toy where the substance or mixture is fully inaccessible to children, including by inhalation.
8. Cosmetic toys, such as play cosmetics for dolls, shall comply with the compositional and labelling requirements laid down in Regulation (EC) No 1223/2009 of the European Parliament and of the Council<sup>1</sup>.

#### **Part 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 for health and safety or any 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, and any cables or other conductors

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<sup>1</sup> Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

through which electricity is conveyed to such parts shall be properly insulated and mechanically protected so as to prevent the risk of such a shock.

3. Electric toys shall 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 shall provide protection against electrical hazards arising from an electrical power source.
5. Electric toys shall provide adequate protection against fire hazards.
6. Electric toys shall be designed and manufactured in such a way that electric, magnetic and electromagnetic fields and other radiations generated by the toy, are limited to the extent necessary for the operation of the toy, and shall operate at a safe level in compliance with the generally acknowledged state of the art, taking account of specific Union measures.
7. Toys which have an electronic control system shall 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 shall 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.

#### **Part V Hygiene**

1. Toys shall be designed and manufactured in such a way with regards to their hygiene and cleanliness that they do not present any risk of infection, sickness or contamination.
2. A toy intended for use by children under 36 months shall 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.
3. Toys with accessible aqueous materials shall be designed and manufactured in such a way as to ensure that they do not present a microbiological risk.

#### **Part VI Radioactivity**

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



## Appendix

### Specific conditions for the presence of certain chemical substances or mixtures in toys

#### Part A. Substances subject to specific limit values

1. The following migration limits, from toys, components of toys or micro-structurally distinct parts 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	2250	560	28130
Antimony	45	11,3	560
Arsenic	3,8	0,9	47
Barium	1 500	375	18750
Boron	1 200	300	15 000
Cadmium	1,3	0,3	17
Chromium (III)	37,5	9,4	460
Chromium (VI)	0,02	0,005	0,053
Cobalt	10,5	2,6	130
Copper	622,5	156	7 700
Lead	2,0	0,5	23
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

These limit values shall not apply to toys or components of toys or micro-structurally distinct parts of toys which, due to their accessibility, function, volume or mass, clearly exclude any risk due to sucking, licking, swallowing or prolonged contact with skin when used as specified in Article 5(2), first subparagraph.

2. Nitrosamines and nitrosable substances are prohibited in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth where the migration of those substances is equal to or higher than 0,01 mg/kg for nitrosamines and 0,1 mg/kg for nitrosable substances.
3. The following limit values, in toys or components of toys or micro-structurally distinct parts of toys, shall not be exceeded:

<b>Substance</b>	<b>CAS No</b>	<b>Limit value and conditions for application</b>
TCEP	115-96-8	5 mg/kg (content limit)

TCPP	13674-84-5	5 mg/kg (content limit)
TDCP	13674-87-8	5 mg/kg (content limit)
Formamide	75-12-7	20 µg/m <sup>3</sup> (emission limit) after a maximum of 28 days from the start of the emission testing of foam toy materials containing more than 200 mg/kg (cut-off limit based on content)
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
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
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.
Formaldehyde	50-00-0	1,5 mg/l (migration limit) in polymeric toy material  0,062 mg/m <sup>3</sup> (emission limit) in wood toy material  30 mg/kg (content limit) in textile toy material  30 mg/kg (content limit) in leather toy material  30 mg/kg (content limit) in paper toy material

		10 mg/kg (content limit) in water-based toy material
Aniline	62-53-3	30 mg/kg (content limit) after reductive cleavage in textile toy material and leather toy material  10 mg/kg (content limit) as free aniline in finger paints  30 mg/kg (content limit) after reductive cleavage in finger paints

4. Toys shall not contain the following fragrance allergens unless their presence in the toy is technically unavoidable under good manufacturing practice and does not exceed 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	150-76-5
(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-butenoate	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
(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
(56)	Atranol (2,6-Dihydroxy-4-methyl-benzaldehyde)	526-37-4
(57)	Chloroatranol (3-Chloro-2,6-Dihydroxy-4-methyl-benzaldehyde)	57074-21-2
(58)	Methyl heptine carbonate	111-12-6

### Part B. Substances subject to specific labelling requirements

- The names of the following fragrance allergens shall be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, as well as in the product passport, if those allergens are added to a toy, where they are present in the toy or any component thereof at concentrations exceeding 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; 1117-61-9; 7540-51-4
(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)	3-methyl-4-(2.6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	127-51-5
(11)	Acetylcedrene	32388-55-9
(12)	Amyl salicylate	2050-08-0
(13)	trans-Anethole	4180-23-8
(14)	Benzaldehyde	100-52-7
(15)	Camphor	76-22-2; 464-49-3
(16)	Carvone	99-49-0; 6485-40-1; 2244-16-8
(17)	beta-Caryophyllene (ox.)	87-44-5
(18)	Rose ketone-4 (Damascenone )	23696-85-7
(19)	alpha-Damascone (TMCHB)	43052-87-5; 23726-94-5
(20)	cis-beta-Damascone	23726-92-3
(21)	delta-Damascone	57378-68-4
(22)	Dimethylbenzyl carbinyl acetate (DMBCA)	151-05-3
(23)	Hexadecanolactone	109-29-5
(24)	Hexamethylindanopyran	1222-05-5
(25)	(DL)-Limonene	138-86-3
(26)	Linayl acetate	115-95-7
(27)	Menthol	1490-04-6; 89-78-1; 2216-51-5
(28)	Methyl salicylate	119-36-8
(29)	3-Methyl-5-(2,2,3-trimethyl-3-cyclopentyl)pent-4-en-2-ol	67801-20-1
(30)	alpha-Pinene	80-56-8
(31)	beta-Pinene	127-91-3
(32)	Propylidene phthalide	17369-59-4
(33)	Salicylaldehyde	90-02-8
(34)	alpha-Santalol	115-71-9
(35)	beta-Santalol	77-42-9
(36)	Sclareol	515-03-7
(37)	alpha-Terpineol	10482-56-1; 98-55-5
(38)	Terpineol (mixture of isomers)	8000-41-7
(39)	Terpinolene	586-62-9

(40)	Tetramethyl acetyloctahydro naphthalenes	54464-57-2; 54464-59-4; 68155-66-8; 68155-67-9
(41)	Trimethyl benzenepropanol (Majantol)	103694-68-4
(42)	Vanillin	121-33-5
(43)	Cananga odorata and Ylang-ylang oil	83863-30-3; 8006-81-3
(44)	Cedrus atlantica bark oil	92201-55-3; 8000-27-9
(45)	Cinnamomum cassia leaf oil	8007-80-5
(46)	Cinnamomum zeylanicum bark oil	84649-98-9
(47)	Citrus aurantium amara flower oil	8016-38-4
(48)	Citrus aurantium amara peel oil	72968-50-4
(49)	Citrus bergamia peel oil expressed	89957-91-5
(50)	Citrus limonum peel oil expressed	84929-31-7
(51)	Citrus sinensis (syn.: Aurantium dulcis) peel oil expressed	97766-30-8; 8028-48-6
(52)	Cymbopogon citratus / schoenanthus oils	89998-14-1; 8007-02-01; 89998-16-3
(53)	Eucalyptus spp. leaf oil	92502-70-0; 8000-48-4
(54)	Eugenia caryophyllus leaf / flower oil	8000-34-8
(55)	Jasminum grandiflorum / officinale	84776-64-7; 90045-94-6; 8022- 96-6
(56)	Juniperus virginiana	8000-27-9; 85085-41-2
(57)	Laurus nobilis fruit oil	8007-48-5
(58)	Laurus nobilis leaf oil	8002-41-3
(59)	Laurus nobilis seed oil	84603-73-6
(60)	Lavandula hybrida	91722-69-9
(61)	Lavandula officinalis	84776-65-8
(62)	Mentha piperita	8006-90-4; 84082-70-2
(63)	Mentha spicata	84696-51-5
(64)	Narcissus spp.	diverse
(65)	Pelargonium graveolens	90082-51-2; 8000-46-2
(66)	Pinus mugo	90082-72-7
(67)	Pinus pumila	97676-05-6
(68)	Pogostemon cablin	8014-09-03; 84238-39-1
(69)	Rose flower oil (Rosa spp.)	Diverse
(70)	Santalum album	84787-70-2; 8006-87-9
(71)	Turpentine (oil)	8006-64-2; 9005-90-7; 8052-14-0

2. The use of fragrances referred to in entries 41 to 55 in the table in Part A, point 4, and of fragrances referred to in points 1 to 10 in the table in point 1 of this Part shall be allowed in olfactory board games, cosmetic kits and gustative games, under the following conditions:

- (a) the fragrances are clearly labelled on the packaging of the toy, and the packaging contains the warning referred to in point 11 of Annex III;
- (b) where applicable, the resulting products made by the child in accordance with the manufacturer's instructions comply with Regulation (EC) No 1223/2009; and
- (c) where applicable, the fragrances comply with the relevant Union 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 2 of Annex III.

**Part C. Permitted uses of substances subject to generic prohibitions under Part III, point 4, of Annex II**

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

### ANNEX III

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

### **1. General rules - presentation**

All warnings shall be preceded by the word 'Warning' or, alternatively, by a generic pictogram such as the following:



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

Toys which might be dangerous for children under 36 months 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 pictogram:



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.

### **3. 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 certain intervals, and pointing out that the toy may cause a fall or overturn if such checks are not carried out.



Instructions shall 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.

#### **4. Functional toys**

Functional toys shall bear the following warning:

‘To be used under the direct supervision of an adult’.

In addition, functional 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 follow such working instructions or take such precautions will expose the user to the hazards normally associated with the appliance or product of which the toy is a scale model or imitation. Those hazards shall be specified in the warning. It shall also be indicated that the toy is to be kept out of the reach of children under a certain age, which shall be specified by the manufacturer.

#### **5. Chemical toys**

Without prejudice to the application of the provisions laid down in applicable Union 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 those substances or mixtures and an indication of the precautions to be taken by the user in order to avoid hazards associated with them. These precautions shall be specified concisely and shall relate to the type of toy. The first aid to be given in the event of serious accidents resulting from the use of the relevant type of toy shall also be mentioned. It shall also be stated that the toy is to be kept out of reach of children under a certain age, which shall be specified by the manufacturer.

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

‘Not suitable for children under ...<sup>2</sup> years. For use under adult supervision’.

#### **6. Skates, roller skates, inline skates, skateboards, scooters and toy bicycles**

Where skates, roller skates, inline skates, skateboards, scooters and toy bicycles are offered for sale as toys, they shall bear the following warning:

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

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

#### **7. Aquatic toys**

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<sup>2</sup> Age to be specified by the manufacturer.

Aquatic toys shall bear the following warning:

‘Only to be used in water in which the child is within his or her depth and under adult supervision’.

### **8. Toys in food**

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

‘Toy inside. Adult supervision recommended’.

### **9. Imitations of protective masks and helmets**

Where imitations of protective masks and helmets are offered for sale as toys, they shall bear the following warning:

‘This toy does not provide protection’.

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

For toys intended to be strung across a cradle, cot or perambulator by means of strings, cords, elastics or straps, the following warning shall be given on the packaging of the toy and shall 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’.

### **11. 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 fragrances referred to in entries 41 to 55 in the table in Part A, point 4, of the Appendix to Annex II and of fragrances referred to in entries 1 to 10 in the table in Part B, point 1, of that Appendix shall contain the following warning:

‘Contains fragrances that may cause allergies’.

**ANNEX IV**  
**CONFORMITY ASSESSMENT PROCEDURES**

**Part I - Module A: Internal production control**

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares, on the manufacturer's sole responsibility, that the toy satisfies the requirements of this Regulation.
2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, to the extent relevant for the assessment, the design, manufacture and operation of the toy. The technical documentation shall contain at least the elements set out in Annex V.
3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of this Regulation.
4. CE marking and product passport
  - 4.1. The manufacturer shall affix the CE marking to each individual toy that satisfies the applicable requirements of this Regulation.
  - 4.2. The manufacturer shall draw up the product passport for a toy model and ensure that together with the technical documentation, it remains available for 10 years after the product has been placed on the market. The product passport shall identify the toy for which it has been drawn up.
5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by the manufacturer's authorised representative, on the manufacturer's behalf and under the manufacturer's responsibility, provided that they are specified in the mandate.

**Part II - Module B : EU-type examination**

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a toy and verifies and attests that the technical design of the toy meets the requirements of this Regulation.
2. EU-type examination may be carried out in any of the following manners:
  - (a) examination of a specimen, representative of the production envisaged, of the complete toy (production type),
  - (b) assessment of the adequacy of the technical design of the toy through an examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production

envisaged, of one or more critical parts of the toy (combination of production type and design type),

- (c) assessment of the adequacy of the technical design of the toy through an examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).

3. The manufacturer shall lodge an application for EU-type examination with a single notified body of the manufacturer's choice.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, as well as the name and address of that representative,
- (b) a written declaration that the same application has not been lodged with any other notified body,
- (c) the technical documentation, which is to make it possible to assess the product's conformity with the applicable requirements of this Regulation and is to include an adequate analysis and assessment of the risk(s), including the safety assessment referred to in Article 21; it is to specify the applicable requirements and cover, to the extent relevant for the assessment, the design, manufacture and operation of the toy; and it is to contain at least the elements set out in Annex V,
- (d) the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme,
- (e) the supporting evidence for the adequacy of the technical design solution; it is to mention any documents that have been used, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full; and it is to include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on the manufacturer's behalf and under the manufacturer's responsibility.

4. The notified body shall:

For the toy:

- 4.1. examine the technical documentation and supporting evidence to assess the adequacy of its technical design;

For the specimen:

- 4.2. verify that the specimen has been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or common specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;
- 4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and/or common specifications, these have been applied correctly;
- 4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards and/or common

specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding essential requirements of the legislative instrument;

- 4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.
5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 as well as their results. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of this Regulation, the notified body shall issue an EU-type examination certificate to the manufacturer. The EU type examination certificate shall include a reference to this Regulation, a colour image, a clear description of the toy, including its dimensions, and a list of the tests performed, together with a reference of the relevant test report. The certificate shall contain the name and address of the manufacturer, an indication of the place of manufacture, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have annexes attached.

The certificate and the annexes thereto shall contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of this Regulation, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type might no longer comply with this Regulation, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the toy with the essential requirements of this Regulation or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform its notifying authorities of the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

Member States, the Commission and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, Member States and the Commission may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.

The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the toy has been placed on the market.
10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

### **Part III- Conformity to type based on internal production control**

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the products concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.
2. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the EU-type examination certificate and with the requirements of the legislative instrument that apply to them.
3. **CE marking and product passport**
  - 3.1. The manufacturer shall affix the CE marking to each individual product that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of the legislative instrument.
  - 3.2. The manufacturer shall create a product passport for a toy model and ensure that it remains available for 10 years after the toy has been placed on the market. The product passport shall identify the toy for which it has been drawn up.
4. **Authorised representative**

The manufacturer's obligations set out in point 3 may be fulfilled by the manufacturer's authorised representative, on the manufacturer's behalf and under the manufacturer's responsibility, provided that they are specified in the mandate.

## **ANNEX V**

### **ELEMENTS TO BE INCLUDED IN THE TECHNICAL DOCUMENTATION**

(as referred to in Article 23)

- (1) 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 substances and mixtures used, to be obtained from the chemical suppliers;
- (2) The safety assessment(s) carried out in accordance with Article 21;
- (3) A description of the conformity assessment procedure followed;
- (4) The addresses of the places of manufacture and storage;
- (5) Copies of documents that the manufacturer has submitted to any notified body,
- (6) 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 22(2); and
- (7) a copy of the EU-type examination certificate, a description of the means whereby the manufacturer ensured conformity of the production with the product type as described in the EU-type examination certificate, and copies of the documents that the manufacturer submitted to the notified body, if the manufacturer submitted the toy to EU-type examination and followed the conformity to type procedure referred to in Article 22(3).

**ANNEX VI**  
**PRODUCT PASSPORT**

**Part I – Information to be included in the product passport**

- (a) unique product identifier of the toy;
- (b) name and address of the manufacturer or of the manufacturer’s authorised representative, as well as the unique operator identifier;
- (c) name and address of the economic operator responsible for carrying out the tasks set out in Article 4 of Regulation (EU) 2019/1020, as well as the unique operator identifier;
- (d) object of the passport (identification of toy allowing traceability, including a colour image of sufficient clarity to enable the identification of the toy);
- (e) the commodity code under which the toy is classified at the moment the passport is created, as set out in Council Regulation (EEC) No 2658/87<sup>3</sup>;
- (f) references to all Union legislation that the toy complies with;
- (g) references to the relevant harmonised standards used, or references to common specifications in relation to which conformity is declared;
- (h) where applicable: the notified body name and number which has intervened in the conformity assessment procedure and issued a certificate, as well as the reference to the certificate;
- (i) the CE marking;
- (j) a list of allergenic fragrances that are present in the toy and that are subject to specific labelling requirements as set out in Part B, point 1, of the Appendix to Annex II;
- (k) any substance of concern that is present in the toy.

**Part II – Information that may be included in the product passport**

- (a) safety information and warnings;
- (b) instructions of use.

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<sup>3</sup> Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).



**ANNEX VII**  
**LIST OF COMMODITY CODES AND PRODUCT DESCRIPTIONS FOR THE  
PURPOSES OF ARTICLE 20(8)**

1	ex 3604; pyrotechnic toys
2	ex 61, ex 62 Fancy dresses for children under 14 years of age, excluding goods classified under 6111, 6112, 6115, 6116, 6209, 6211, 6212, 6213, 6216
3	ex 8711, ex 8712, ex 8714 Children's cycles, whether or not motorised, and parts thereof.
4	ex 9503 Tricycles, scooters, pedal cars and similar wheeled toys; dolls' carriages; dolls; other toys; reduced-size ('scale') models and similar recreational models, working or not; puzzles of all kinds
5	ex 9505 Festive, carnival or other entertainment articles, including conjuring tricks and novelty jokes

**ANNEX VIII**  
**CORRELATION TABLE**

<b>Directive 2009/48/EC</b>	<b>This Regulation</b>
Article 1	Article 1
Article 2(1)	Article 2(1)
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Article 3(6)	Article 3(6)
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Article 3(8)	Article 3(10)
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Article 3(10)	Article 3(22)
Article 3(11)	Article 3(20)
Article 3(12)	Article 3(21)
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Article 3(24)	Article 3(34)
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Article 3(26)	-
Article 3(27)	Article 3(24)
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Article 4(2)	Article 7(2)
Article 4(3)	Article 7(3)
Article 4(4)	Article 7(4)
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Article 14	-
Article 15	-
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Article 16(2)	Article 15 second subparagraph
Article 16(3)	-
Article 16(4)	Article 4(2)

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Article 21(3)	Article 23(3)
Article 21(4)	Article 23(4)
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Article 23(4)	Article 25(4)
Article 24(1)	Article 26(1)
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Article 24(3)	Article 26(3)
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Article 26(3)	Article 28(3)

Article 26(4)	Article 28(4)
Article 26(5)	Article 28(5)
Article 26(6)	Article 28(6)
Article 26(7)	Article 28(7)
Article 26(8)	Article 28(8)
Article 26(9)	Article 28(9)
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Article 29(3)	Article 30(4)
Article 29(4)	Article 30(5)
Article 30(1)	Article 31(1)
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Article 30(3)	-
Article 31(1)	Article 32(1)
Article 31(2)	Article 32(2)
Article 31(3)	Article 32(3)
Article 31(4)	-
Article 31(5)	Article 32(4)
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Article 32(2)	Article 33(2)
Article 33(1)	Article 34(1)

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Article 34(1)	Article 35(1)
Article 34(2)	Article 35(2)
Article 34(3)	Article 35(3)
Article 34(4)	Article 35(4)
Article 35(1)	Article 36(1)
Article 35(2)	Article 36(2)
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Article 35(4)	Article 36(4)
Article 35(5)	Article 36(5)
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Article 42(3)	Article 41(3)
Article 42(4)	Article 41(4)
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Article 42(6)	Article 41(6)
Article 42(7)	Article 41(7)
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Article 45(1)	Article 43(1)
Article 45(2)	Article 43(2)
Article 46	-
Article 47(1)	Article 47(1)
Article 47(2)	-
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