



REACH Annex XVII the latest revision

RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES

2021.9.13 updated

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
1. Polychlorinated terphenyls (PCTs)	Shall not be placed on the market, or used: <ul style="list-style-type: none"> — as substances, — in mixtures, including waste oils, or in equipment, in concentrations greater than 50 mg/kg (0,005 % by weight).
2. Chloroethene (vinyl chloride) CAS No 75-01-4 EC No 200-831-0	Shall not be used as propellant in aerosols for any use. Aerosols dispensers containing the substance as propellant shall not be placed on the market.
3. Liquid substances or mixtures fulfilling 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.	<ol style="list-style-type: none"> Shall not be used in: <ul style="list-style-type: none"> — ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays, — tricks and jokes, — games for one or more participants, or any article intended to be used as such, even with ornamental aspects, Articles not complying with paragraph 1 shall not be placed on the market. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they: <ul style="list-style-type: none"> — can be used as fuel in decorative oil lamps for supply to the general public, and — present an aspiration hazard and are labelled with H304. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN). Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met: <ol style="list-style-type: none"> lamp oils, labelled with H304, intended for supply to the general



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	<p>public are visibly, legibly and indelibly marked as follows: 'Keep lamps filled with this liquid out of the reach of children'; and, by 1 December 2010, 'Just a sip of lamp oil – or even sucking the wick of lamps – may lead to life-threatening lung damage';</p> <p>(b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: 'Just a sip of grill lighter fluid may lead to life threatening lung damage';</p> <p>(c) lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.</p>
<p>4. Tris (2,3 dibromopropyl) phosphate CAS No 126-72-7</p>	<p>1. Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin.</p> <p>2. Articles not complying with paragraph 1 shall not be placed on the market.</p>
<p>5. Benzene CAS No 71-43-2 EC No 200-753-7</p>	<p>1. Shall not be used in toys or parts of toys where the concentration of benzene in the free state is greater than 5 mg/kg (0,0005 %) of the weight of the toy or part of toy.</p> <p>2. Toys and parts of toys not complying with paragraph 1 shall not be placed on the market.</p> <p>3. Shall not be placed on the market, or used,</p> <ul style="list-style-type: none"> — as a substance, — as a constituent of other substances, or in mixtures, in concentrations equal to, or greater than 0,1 % by weight. <p>4. However, paragraph 3 shall not apply to:</p> <p>(a) motor fuels which are covered by Directive 98/70/EC;</p> <p>(b) substances and mixtures for use in industrial processes not allowing for the emission of benzene in quantities in excess of those laid down in existing legislation;</p> <p>(c) natural gas placed on the market for use by consumers, provided that the concentration of benzene remains below 0,1 % volume/volume.</p>
<p>6. Asbestos fibres</p> <p>(a) Crocidolite CAS No 12001-28-4</p> <p>(b) Amosite CAS No 12172-73-5</p> <p>(c) Anthophyllite CAS No 77536-67-5</p> <p>(d) Actinolite CAS No 77536-66-4</p> <p>(e) Tremolite CAS No 77536-68-6</p> <p>(f) Chrysotile</p>	<p>1. The manufacture, placing on the market and use of these fibres and of articles and mixtures containing these fibres added intentionally is prohibited.</p> <p>However, if the use of diaphragms containing chrysotile for electrolysis installations in use on 13 July 2016 had been exempted by a Member State in accordance with the version of this paragraph in force until that date, the first subparagraph shall not apply until 1 July 2025 to the use in those installations of such diaphragms or of chrysotile used exclusively in the maintenance of such diaphragms, provided that such use is carried out in compliance with the conditions of a permit set in accordance with Directive 2010/75/EU of the European Parliament and of the Council.</p> <p>Any downstream user benefiting from such an exemption shall send, by 31</p>



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<p>CAS No 12001-29-5 CAS No 132207-32-0</p>	<p>January of each calendar year to the Member State in which the relevant electrolysis installation is located, a report indicating the amount of chrysotile used in diaphragms pursuant to the exemption. The Member State shall transmit a copy to the European Commission.</p> <p>Where, in order to protect the health and safety of workers, a Member State requires monitoring of chrysotile in air by downstream users, the results shall be included in that report.</p> <p>2. The use of articles containing asbestos fibres referred to in paragraph 1 which were already installed and/or in service before 1 January 2005 shall continue to be permitted until they are disposed of or reach the end of their service life. However, Member States may, for reasons of protection of human health, restrict, prohibit or make subject to specific conditions, the use of such articles before they are disposed of or reach the end of their service life.</p> <p>Member States may allow placing on the market of articles in their entirety containing asbestos fibres referred to in paragraph 1 which were already installed and/or in service before 1 January 2005, under specific conditions ensuring a high level of protection of human health. Member States shall communicate these national measures to the Commission by 1 June 2011. The Commission shall make this information publicly available.</p> <p>3. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, the placing on the market and use of articles containing these fibres, as permitted according to the preceding derogations, shall be permitted only if suppliers ensure before the placing on the market that articles bear a label in accordance with Appendix 7 to this Annex.</p>
<p>7. Tris(aziridinyl)phosphin oxide CAS No 545-55-1 EC No 208-892-5</p>	<p>1. Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin.</p> <p>2. Articles not complying with paragraph 1 shall not be placed on the market.</p>
<p>8. Polybromobiphenyls; Polybrominatedbiphenyls (PBB) CAS No 59536-65-1</p>	<p>1. Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin.</p> <p>2. Articles not complying with paragraph 1 shall not be placed on the market.</p>
<p>9. (a) Soap bark powder (Quillaja saponaria) and its derivatives containing saponines CAS No 68990-67-0 EC No 273-620-4 (b) Powder of the roots of</p>	<p>1. Shall not be used, in jokes and hoaxes or in mixtures or articles intended to be used as such, for instance as a constituent of sneezing powder and stink bombs.</p> <p>2. Jokes and hoaxes, or mixtures or articles intended to be used as such, not complying with paragraph 1 shall not be placed on the market.</p> <p>3. However, paragraphs 1 and 2 shall not apply to stink bombs containing not more than 1,5 ml of liquid.</p>



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<p>Helleborus viridis and Helleborus niger</p> <p>(c) Powder of the roots of Veratrum album and Veratrum nigrum</p> <p>(d) Benzidine and/or its derivatives</p> <p>CAS No 92-87-5</p> <p>EC No 202-199-1</p> <p>(e) o-Nitrobenzaldehyde</p> <p>CAS No 552-89-6</p> <p>EC No 209-025-3</p> <p>(f) Wood powder</p>	
<p>10.</p> <p>(a) Ammonium sulphide</p> <p>CAS No 12135-76-1</p> <p>EC No 235-223-4</p> <p>(b) Ammonium hydrogen sulphide</p> <p>CAS No 12124-99-1</p> <p>EC No 235-184-3</p> <p>(c) Ammonium polysulphide</p> <p>CAS No 9080-17-5</p> <p>EC No 232-989-1</p>	<p>1. Shall not be used, in jokes and hoaxes or in mixtures or articles intended to be used as such, for instance as a constituent of sneezing powder and stink bombs.</p> <p>2. Jokes and hoaxes, or mixtures or articles intended to be used as such, not complying with paragraph 1 shall not be placed on the market.</p> <p>3. However, paragraphs 1 and 2 shall not apply to stink bombs containing not more than 1,5 ml of liquid.</p>
<p>11. Volatile esters of bromoacetic acids:</p> <p>(a) Methyl bromoacetate</p> <p>CAS No 96-32-2</p> <p>EC No 202-499-2</p> <p>(b) Ethyl bromoacetate</p> <p>CAS No 105-36-2</p> <p>EC No 203-290-9</p> <p>(c) Propyl bromoacetate</p> <p>CAS No 35223-80-4</p> <p>(d) Butyl bromoacetate</p> <p>CAS No 18991-98-5</p> <p>EC No 242-729-9</p>	<p>1. Shall not be used, in jokes and hoaxes or in mixtures or articles intended to be used as such, for instance as a constituent of sneezing powder and stink bombs.</p> <p>2. Jokes and hoaxes, or mixtures or articles intended to be used as such, not complying with paragraph 1 shall not be placed on the market.</p> <p>3. However, paragraphs 1 and 2 shall not apply to stink bombs containing not more than 1,5 ml of liquid.</p>
<p>12. 2-Naphthylamine</p> <p>CAS No 91-59-8</p> <p>EC No 202-080-4 and its salts</p> <p>13. Benzidine</p> <p>CAS No 92-87-5</p>	<p>The following shall apply to entries 12 to 15:</p> <p>Shall not be placed on the market, or used, as substances or in mixtures in concentrations greater than 0,1 % by weight.</p>



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<p>EC No 202-199-1 and its salts</p> <p>14. 4-Nitrobiphenyl CAS No 92-93-3 Einecs EC No 202-204-7</p> <p>15. 4-Aminobiphenyl xenylamine CAS No 92-67-1 Einecs EC No 202-177-1 and its salts</p>	
<p>16. Lead carbonates:</p> <p>(a) Neutral anhydrous carbonate (PbCO₃) CAS No 598-63-0 EC No 209-943-4</p> <p>(b) Trilead-bis(carbonate)-dihydroxide 2Pb CO₃-Pb(OH)₂ CAS No 1319-46-6 EC No 215-290-6</p>	<p>Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint.</p> <p>However, Member States may, in accordance with the provisions of International Labour Organization (ILO) Convention 13, permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors, as well as the placing on the market for such use. Where a Member State makes use of this derogation, it shall inform the Commission thereof.</p>
<p>17. Lead sulphates:</p> <p>(a) PbSO₄ CAS No 7446-14-2 EC No 231-198-9</p> <p>(b) Pb_x SO₄ CAS No 15739-80-7 EC No 239-831-0</p>	<p>Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint.</p> <p>However, Member States may, in accordance with the provisions of International Labour Organization (ILO) Convention 13, permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors, as well as the placing on the market for such use. Where a Member State makes use of this derogation, it shall inform the Commission thereof.</p>
<p>18. Mercury compounds</p>	<p>Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use:</p> <p>(a) to prevent the fouling by micro-organisms, plants or animals of:</p> <ul style="list-style-type: none"> — the hulls of boats, — cages, floats, nets and any other appliances or equipment used for fish or shellfish farming, — any totally or partly submerged appliances or equipment; <p>(b) in the preservation of wood;</p> <p>(c) in the impregnation of heavy-duty industrial textiles and yarn intended for their manufacture;</p> <p>(d) in the treatment of industrial waters, irrespective of their use.</p>
<p>18a. Mercury CAS No 7439-97-6 EC No 231-106-7</p>	<p>1. Shall not be placed on the market:</p> <p>(a) in fever thermometers;</p> <p>(b) in other measuring devices intended for sale to the general public</p>



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	<p>(such as manometers, barometers, sphygmomanometers, thermometers other than fever thermometers).</p> <p>2. The restriction in paragraph 1 shall not apply to measuring devices that were in use in the Community before 3 April 2009. However Member States may restrict or prohibit the placing on the market of such measuring devices.</p> <p>3. The restriction in paragraph 1(b) shall not apply to:</p> <ul style="list-style-type: none"> (a) measuring devices more than 50 years old on 3 October 2007; (b) barometers (except barometers within point (a)) until 3 October 2009. <p>5. The following mercury-containing measuring devices intended for industrial and professional uses shall not be placed on the market after 10 April 2014:</p> <ul style="list-style-type: none"> (a) barometers; (b) hygrometers; (c) manometers; (d) sphygmomanometers; (e) strain gauges to be used with plethysmographs; (f) tensiometers; (g) thermometers and other non-electrical thermometric applications. <p>The restriction shall also apply to measuring devices under points (a) to (g) which are placed on the market empty if intended to be filled with mercury.</p> <p>6. The restriction in paragraph 5 shall not apply to:</p> <ul style="list-style-type: none"> (a) sphygmomanometers to be used: <ul style="list-style-type: none"> (i) in epidemiological studies which are ongoing on 10 October 2012; (ii) as reference standards in clinical validation studies of mercury-free sphygmomanometers; (b) thermometers exclusively intended to perform tests according to standards that require the use of mercury thermometers until 10 October 2017; (c) mercury triple point cells which are used for the calibration of platinum resistance thermometers. <p>7. The following mercury-using measuring devices intended for professional and industrial uses shall not be placed on the market after 10 April 2014:</p> <ul style="list-style-type: none"> (a) mercury pycnometers; (b) mercury metering devices for determination of the softening point. <p>8. The restrictions in paragraphs 5 and 7 shall not apply to:</p> <ul style="list-style-type: none"> (a) measuring devices more than 50 years old on 3 October 2007; (b) measuring devices which are to be displayed in public exhibitions for cultural and historical purposes.
19. Arsenic compounds	<p>1. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use to prevent the fouling by micro-organisms, plants or animals of:</p>



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- the hulls of boats,
- cages, floats, nets and any other appliances or equipment used for fish or shellfish farming,
- any totally or partly submerged appliances or equipment.

2. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use in the treatment of industrial waters, irrespective of their use.

3. Shall not be used in the preservation of wood. Furthermore, wood so treated shall not be placed on the market.

4. By way of derogation from paragraph 3:

(a) Relating to the substances and mixtures for the preservation of wood: these may only be used in industrial installations using vacuum or pressure to impregnate wood if they are solutions of inorganic compounds of the copper, chromium, arsenic (CCA) type C and if they are authorised in accordance with Article 5(1) of Directive 98/8/EC. Wood so treated shall not be placed on the market before fixation of the preservative is completed.

(b) Wood treated with CCA solution in accordance with point (a) may be placed on the market for professional and industrial use provided that the structural integrity of the wood is required for human or livestock safety and skin contact by the general public during its service life is unlikely:

- as structural timber in public and agricultural buildings, office buildings, and industrial premises,
- in bridges and bridgework,
- as constructional timber in freshwater areas and brackish waters, for example jetties and bridges,
- as noise barriers,
- in avalanche control,
- in highway safety fencing and barriers,
- as debarked round conifer livestock fence posts,
- in earth retaining structures,
- as electric power transmission and telecommunications poles,
- as underground railway sleepers.

(c) Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that all treated wood placed on the market is individually labelled 'For professional and industrial installation and use only, contains arsenic'. In addition, all wood placed on the market in packs shall also bear a label stating 'Wear gloves when handling this wood. Wear a dust mask and eye protection when cutting or otherwise crafting this wood. Waste from this wood shall be treated as hazardous by an authorised undertaking'.

(d) Treated wood referred to under point (a) shall not be used:



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	<ul style="list-style-type: none"> — in residential or domestic constructions, whatever the purpose, — in any application where there is a risk of repeated skin contact, — in marine waters, — for agricultural purposes other than for livestock fence posts and structural uses in accordance with point (b), — in any application where the treated wood may come into contact with intermediate or finished products intended for human and/or animal consumption. <p>5. Wood treated with arsenic compounds that was in use in the Community before 30 September 2007, or that was placed on the market in accordance with paragraph 4 may remain in place and continue to be used until it reaches the end of its service life.</p> <p>6. Wood treated with CCA type C that was in use in the Community before 30 September 2007, or that was placed on the market in accordance with paragraph 4:</p> <ul style="list-style-type: none"> — may be used or reused subject to the conditions pertaining to its use listed under points 4(b), (c) and (d), — may be placed on the market subject to the conditions pertaining to its use listed under points 4(b), (c) and (d). <p>7. Member States may allow wood treated with other types of CCA solutions that was in use in the Community before 30 September 2007:</p> <ul style="list-style-type: none"> — to be used or reused subject to the conditions pertaining to its use listed under points 4 (b), (c) and (d), — to be placed on the market subject to the conditions pertaining to its use listed under points 4(b), (c) and (d).
20. Organostannic compounds	<p>1. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is acting as biocide in free association paint.</p> <p>2. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture acts as biocide to prevent the fouling by micro-organisms, plants or animals of:</p> <ul style="list-style-type: none"> (a) all craft irrespective of their length intended for use in marine, coastal, estuarine and inland waterways and lakes; (b) cages, floats, nets and any other appliances or equipment used for fish or shellfish farming; (c) any totally or partly submerged appliance or equipment. <p>3. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use in the treatment of industrial waters.</p> <p>4. Tri-substituted organostannic compounds:</p> <ul style="list-style-type: none"> (a) Tri-substituted organostannic compounds such as tributyltin (TBT) compounds and triphenyltin (TPT) compounds shall not be used after 1 July 2010 in articles where the concentration in the article, or part thereof,



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is greater than the equivalent of 0,1 % by weight of tin.

(b) Articles not complying with point (a) shall not be placed on the market after 1 July 2010, except for articles that were already in use in the Community before that date.

5. Dibutyltin (DBT) compounds:

(a) Dibutyltin (DBT) compounds shall not be used after 1 January 2012 in mixtures and articles for supply to the general public where the concentration in the mixture or the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin.

(b) Articles and mixtures not complying with point (a) shall not be placed on the market after 1 January 2012, except for articles that were already in use in the Community before that date.

(c) By way of derogation, points (a) and (b) shall not apply until 1 January 2015 to the following articles and mixtures for supply to the general public:

- one-component and two-component room temperature vulcanisation sealants (RTV-1 and RTV-2 sealants) and adhesives,
- paints and coatings containing DBT compounds as catalysts when applied on articles,
- soft polyvinyl chloride (PVC) profiles whether by themselves or coextruded with hard PVC,
- fabrics coated with PVC containing DBT compounds as stabilisers when intended for outdoor applications,
- outdoor rainwater pipes, gutters and fittings, as well as covering material for roofing and façades,

(d) By way of derogation, points (a) and (b) shall not apply to materials and articles regulated under Regulation (EC) No 1935/2004.

6. Dioctyltin (DOT) compound:

(a) Dioctyltin (DOT) compounds shall not be used after 1 January 2012 in the following articles for supply to, or use by, the general public, where the concentration in the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin:

- textile articles intended to come into contact with the skin,
- gloves,
- footwear or part of footwear intended to come into contact with the skin,
- wall and floor coverings,
- childcare articles,
- female hygiene products,
- nappies,
- two-component room temperature vulcanisation moulding kits (RTV-2 moulding kits).

(b) Articles not complying with point (a) shall not be placed on the market after 1 January 2012, except for articles that were already in use in



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	the Community before that date.
<p>21.</p> <p>Di-μ-oxo-di-n-butylstanniohydroxyborane/Dibutyltin hydrogen borate C₈H₁₉BO₃Sn (DBB)</p> <p>CAS No 75113-37-0</p> <p>EC No 401-040-5</p>	<p>Shall not be placed on the market, or used, as a substance, or in mixtures in a concentration equal to, or greater than 0,1 % by weight.</p> <p>However, the first paragraph shall not apply to this substance (DBB) or mixtures containing it if these are intended solely for conversion into articles, among which this substance will no longer feature in a concentration equal to or greater than 0,1 %.</p>
<p>23. Cadmium</p> <p>CAS No 7440-43-9</p> <p>EC No 231-152-8 and its compounds</p>	<p>For the purpose of this entry, the codes and chapters indicated in square brackets are the codes and chapters of the tariff and statistical nomenclature of Common Customs Tariff as established by Council Regulation (EEC) No 2658/87.</p> <p>1. Shall not be used in mixtures and articles produced from the following synthetic organic polymers (hereafter referred to as plastic material):</p> <ul style="list-style-type: none"> — polymers or copolymers of vinyl chloride (PVC) [3904 10] [3904 21] — polyurethane (PUR) [3909 50] — low-density polyethylene (LDPE), with the exception of low-density polyethylene used for the production of coloured masterbatch [3901 10] — cellulose acetate (CA) [3912 11] — cellulose acetate butyrate (CAB) [3912 11] — epoxy resins [3907 30] — melamine-formaldehyde (MF) resins [3909 20] — urea-formaldehyde (UF) resins [3909 10] — unsaturated polyesters (UP) [3907 91] — polyethylene terephthalate (PET) [3907 60] — polybutylene terephthalate (PBT) — transparent/general-purpose polystyrene [3903 11] — acrylonitrile methylmethacrylate (AMMA) — cross-linked polyethylene (VPE) — high-impact polystyrene — polypropylene (PP) [3902 10] <p>Mixtures and articles produced from plastic material as listed above shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight of the plastic material.</p> <p>By way of derogation, the second subparagraph shall not apply to articles placed on the market before 10 December 2011.</p> <p>The first and second subparagraphs apply without prejudice to Council Directive 94/62/EC and acts adopted on its basis.</p> <p>By 19 November 2012, in accordance with Article 69, the Commission shall ask the European Chemicals Agency to prepare a dossier conforming to the requirements of Annex XV in order to assess whether the use of cadmium and its compounds in plastic material, other than that</p>



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listed in subparagraph 1, should be restricted.

2. Shall not be used or placed on the market in paints with codes [3208] [3209] in a concentration (expressed as Cd metal) equal to or greater than 0,01 % by weight.

For paints with codes [3208] [3209] with a zinc content exceeding 10 % by weight of the paint, the concentration of cadmium (expressed as Cd metal) shall not be equal to or greater than 0,1 % by weight.

Painted articles shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,1 % by weight of the paint on the painted article.

3. By way of derogation, paragraphs 1 and 2 shall not apply to articles coloured with mixtures containing cadmium for safety reasons.

4. By way of derogation, paragraph 1, second subparagraph shall not apply to:

— mixtures produced from PVC waste, hereinafter referred to as 'recovered PVC',

— mixtures and articles containing recovered PVC if their concentration of cadmium (expressed as Cd metal) does not exceed 0,1 % by weight of the plastic material in the following rigid PVC applications:

- (a) profiles and rigid sheets for building applications;
- (b) doors, windows, shutters, walls, blinds, fences, and roof gutters;
- (c) decks and terraces;
- (d) cable ducts;
- (e) pipes for non-drinking water if the recovered PVC is used in the middle layer of a multilayer pipe and is entirely covered with a layer of newly produced PVC in compliance with paragraph 1 above.

Suppliers shall ensure, before the placing on the market of mixtures and articles containing recovered PVC for the first time, that these are visibly, legibly and indelibly marked as follows: 'Contains recovered PVC' or with the following pictogram:



In accordance with Article 69 of this Regulation, the derogation granted in paragraph 4 will be reviewed, in particular with a view to reducing the limit value for cadmium and to reassess the derogation for the applications listed in points (a) to (e), by 31 December 2017.

5. For the purpose of this entry, 'cadmium plating' means any deposit or coating of metallic cadmium on a metallic surface.

Shall not be used for cadmium plating metallic articles or components of the articles used in the following sectors/applications:



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(a) equipment and machinery for:

- food production [8210] [8417 20] [8419 81] [8421 11] [8421 22] [8422] [8435] [8437] [8438] [8476 11]
- agriculture [8419 31] [8424 81] [8432] [8433] [8434] [8436]
- cooling and freezing [8418]
- printing and book-binding [8440] [8442] [8443]

(b) equipment and machinery for the production of:

- household goods [7321] [8421 12] [8450] [8509] [8516]
- furniture [8465] [8466] [9401] [9402] [9403] [9404]
- sanitary ware [7324]
- central heating and air conditioning plant [7322] [8403] [8404] [8415]

In any case, whatever their use or intended final purpose, the placing on the market of cadmium-plated articles or components of such articles used in the sectors/applications listed in points (a) and (b) above and of articles manufactured in the sectors listed in point (b) above is prohibited.

6. The provisions referred to in paragraph 5 shall also be applicable to cadmium-plated articles or components of such articles when used in the sectors/applications listed in points (a) and (b) below and to articles manufactured in the sectors listed in (b) below:

(a) equipment and machinery for the production of:

- paper and board [8419 32] [8439] [8441] textiles and clothing [8444] [8445] [8447] [8448] [8449] [8451] [8452]

(b) equipment and machinery for the production of:

- industrial handling equipment and machinery [8425] [8426] [8427] [8428] [8429] [8430] [8431]
- road and agricultural vehicles [chapter 87]
- rolling stock [chapter 86]
- vessels [chapter 89]

7. However, the restrictions in paragraphs 5 and 6 shall not apply to:

- articles and components of the articles used in the aeronautical, aerospace, mining, offshore and nuclear sectors whose applications require high safety standards and in safety devices in road and agricultural vehicles, rolling stock and vessels,
- electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed.

8. Shall not be used in brazing fillers in concentration equal to or greater than 0,01 % by weight.

Brazing fillers shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight.

For the purpose of this paragraph brazing shall mean a joining technique using alloys and undertaken at temperatures above 450 °C.



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	<p>9. By way of derogation, paragraph 8 shall not apply to brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons.</p> <p>10. Shall not be used or placed on the market if the concentration is equal to or greater than 0,01 % by weight of the metal in:</p> <p>(i) metal beads and other metal components for jewellery making;</p> <p>(ii) metal parts of jewellery and imitation jewellery articles and hair accessories, including:</p> <ul style="list-style-type: none"> — bracelets, necklaces and rings, — piercing jewellery, — wrist-watches and wrist-wear, — brooches and cufflinks. <p>11. By way of derogation, paragraph 10 shall not apply to articles placed on the market before 10 December 2011 and jewellery more than 50 years old on 10 December 2011.</p>
<p>24. Monomethyl — tetrachlorodiphenyl methane Trade name: Ugilec 141 CAS No 76253-60-6</p>	<p>1. Shall not be placed on the market, or used, as a substance or in mixtures. Articles containing the substance shall not be placed on the market.</p> <p>2. By way of derogation, paragraph 1 shall not apply:</p> <p>(a) in the case of plant and machinery already in service on 18 June 1994, until such plant and machinery is disposed of;</p> <p>(b) in the case of the maintenance of plant and machinery already in service within a Member State on 18 June 1994.</p> <p>For the purposes of point (a) Member States may, on grounds of human health protection and environmental protection, prohibit within their territory the use of such plant or machinery before it is disposed of.</p>
<p>25. Monomethyl-dichloro-diphenyl methane Trade name: Ugilec 121 Ugilec 21</p>	<p>Shall not be placed on the market, or used, as a substance or in mixtures. Articles containing the substance shall not be placed on the market.</p>
<p>26. Monomethyl-dibromo-diphenyl methane bromobenzylbromotoluene, mixture of isomers Trade name: DBBT CAS No 99688-47-8</p>	<p>Shall not be placed on the market, or used, as a substance or in mixtures. Articles containing the substance shall not be placed on the market.</p>
<p>27. Nickel CAS No 7440-02-0 EC No 231-111-4 and its compounds</p>	<p>1. Shall not be used:</p> <p>(a) in any post assemblies which are inserted into pierced ears and other pierced parts of the human body unless the rate of nickel release from such post assemblies is less than 0,2 µg/cm²/week (migration limit);</p> <p>(b) in articles intended to come into direct and prolonged contact with the</p>



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	<p>skin such as:</p> <ul style="list-style-type: none"> — earrings, — necklaces, bracelets and chains, anklets, finger rings, — wrist-watch cases, watch straps and tighteners, — rivet buttons, tighteners, rivets, zippers and metal marks, when these are used in garments, <p>if the rate of nickel release from the parts of these articles coming into direct and prolonged contact with the skin is greater than 0,5 µg/cm²/week.</p> <p>(c) in articles referred to in point (b) where these have a non-nickel coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of such articles coming into direct and prolonged contact with the skin will not exceed 0,5 µg/cm²/week for a period of at least two years of normal use of the article.</p> <p>2. Articles which are the subject of paragraph 1 shall not be placed on the market unless they conform to the requirements set out in that paragraph.</p> <p>3. The standards adopted by the European Committee for Standardisation (CEN) shall be used as the test methods for demonstrating the conformity of articles to paragraphs 1 and 2.</p>
<p>28. Substances which are classified as carcinogen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 1 or Appendix 2, respectively.</p> <p>29. Substances which are classified as germ cell mutagen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 3 or Appendix 4, respectively.</p> <p>30. Substances which are classified as reproductive toxicant category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 5 or Appendix 6, respectively.</p>	<p>Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30:</p> <p>1. Shall not be placed on the market, or used,</p> <ul style="list-style-type: none"> — as substances, — as constituents of other substances, or, — in mixtures, <p>for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:</p> <ul style="list-style-type: none"> — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, — the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008. <p>Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows:</p> <p>‘Restricted to professional users’.</p> <p>2. By way of derogation, paragraph 1 shall not apply to:</p> <ul style="list-style-type: none"> (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC; (c) the following fuels and oil products:



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	<ul style="list-style-type: none"> — motor fuels which are covered by Directive 98/70/EC, — mineral oil products intended for use as fuel in mobile or fixed combustion plants, — fuels sold in closed systems (e.g. liquid gas bottles); <p>(d) artists' paints covered by Regulation (EC) No 1272/2008;</p> <p>(e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date;</p> <p>(f) devices covered by Regulation (EU) 2017/745.</p>
<p>31.</p> <p>(a) Creosote; wash oil CAS No 8001-58-9 EC No 232-287-5</p> <p>(b) Creosote oil; wash oil CAS No 61789-28-4 EC No 263-047-8</p> <p>(c) Distillates (coal tar), naphthalene oils; naphthalene oil CAS No 84650-04-4 EC No 283-484-8</p> <p>(d) Creosote oil, acenaphthene fraction; wash oil CAS No 90640-84-9 EC No 283-484-8EC No 292-605-3</p> <p>(e) Distillates (coal tar), upper; heavy anthracene oil CAS No 65996-91-0 EC No 266-026-1</p> <p>(f) Anthracene oil CAS No 90640-80-5 EC No 292-602-7</p> <p>(g) Tar acids, coal, crude; crude phenols CAS No 65996-85-2 EC No 266-019-3</p>	<p>1. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for the treatment of wood. Furthermore, wood so treated shall not be placed on the market.</p> <p>2. By way of derogation from paragraph 1:</p> <p>(a) The substances and mixtures may be used for wood treatment in industrial installations or by professionals covered by Community legislation on the protection of workers for in situ retreatment only if they contain:</p> <p>(i) benzo[a]pyrene at a concentration of less than 50 mg/kg (0,005 % by weight), and</p> <p>(ii) water extractable phenols at a concentration of less than 3 % by weight.</p> <p>Such substances and mixtures for use in wood treatment in industrial installations or by professionals:</p> <ul style="list-style-type: none"> — may be placed on the market only in packaging of a capacity equal to or greater than 20 litres, — shall not be sold to consumers. <p>Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is visibly, legibly and indelibly marked as follows:</p> <p>‘For use in industrial installations or professional treatment only’.</p> <p>(b) Wood treated in industrial installations or by professionals according to subparagraph (a) which is placed on the market for the first time or retreated in situ may be used for professional and industrial use only, for example on railways, in electric power transmission and telecommunications, for fencing, for agricultural purposes (for example stakes for tree support) and in harbours and waterways.</p> <p>(c) The prohibition in paragraph 1 on the placing on the market shall not apply to wood which has been treated with substances listed in entry 31 (a) to (i) before 31 December 2002 and is placed on the second-hand market for re-use.</p> <p>3. Treated wood referred to under paragraph 2(b) and (c) shall not be</p>



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<p>(h) Creosote, wood CAS No 8021-39-4 EC No 232-419-1</p> <p>(i) Low temperature tar oil, alkaline; extract residues (coal), low temperature coal tar alkaline CAS No 122384-78-5 EC No 310-191-5</p>	<p>used:</p> <ul style="list-style-type: none"> — inside buildings, whatever their purpose, — in toys, — in playgrounds, — in parks, gardens, and outdoor recreational and leisure facilities where there is a risk of frequent skin contact, — in the manufacture of garden furniture such as picnic tables, — for the manufacture and use and any re-treatment of: <ul style="list-style-type: none"> — containers intended for growing purposes, — packaging that may come into contact with raw materials, intermediate or finished products destined for human and/or animal consumption, — other materials which may contaminate the articles mentioned above.
<p>32. Chloroform CAS No 67-66-3 EC No 200-663-8</p> <p>34. 1,1,2-Trichloroethane CAS No 79-00-5 EC No 201-166-9</p> <p>35. 1,1,2,2-Tetrachloroethane CAS No 79-34-5 EC No 201-197-8</p> <p>36. 1,1,1,2-Tetrachloroethane CAS No 630-20-6</p> <p>37. Pentachloroethane CAS No 76-01-7 EC No 200-925-1</p> <p>38. 1,1-Dichloroethene CAS No 75-35-4 EC No 200-864-0</p>	<p>Without prejudice to the other parts of this Annex, the following shall apply to entries 32 to 38.</p> <p>1. Shall not be placed on the market, or used,</p> <ul style="list-style-type: none"> — as substances, — as constituents of other substances, or in mixtures in concentrations equal to or greater than 0,1 % by weight, <p>where the substance or mixture is intended for supply to the general public and/or is intended for diffusive applications such as in surface cleaning and cleaning of fabrics.</p> <p>2. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures containing them in concentrations equal to or greater than 0,1 % by weight is visibly, legibly and indelibly marked as follows:</p> <p>‘For use in industrial installations only’.</p> <p>By way of derogation this provision shall not apply to:</p> <p>(a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC;</p> <p>(b) cosmetic products as defined by Directive 76/768/EEC.</p>
<p>40. Substances classified as flammable gases category 1 or 2, flammable liquids categories 1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases,</p>	<p>1. Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended for supply to the general public for entertainment and decorative purposes such as the following:</p> <ul style="list-style-type: none"> — metallic glitter intended mainly for decoration, — artificial snow and frost, — ‘whoopie’ cushions, — silly string aerosols,



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category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids category 1, regardless of whether they appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or not.	<ul style="list-style-type: none"> — imitation excrement, — horns for parties, — decorative flakes and foams, — artificial cobwebs, — stink bombs. <p>2. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances, suppliers shall ensure before the placing on the market that the packaging of aerosol dispensers referred to above is marked visibly, legibly and indelibly with: 'For professional users only'.</p> <p>3. By way of derogation, paragraphs 1 and 2 shall not apply to the aerosol dispensers referred to Article 8 (1a) of Council Directive 75/324/EEC.</p> <p>4. The aerosol dispensers referred to in paragraphs 1 and 2 shall not be placed on the market unless they conform to the requirements indicated.</p>
41. Hexachloroethane CAS No 67-72-1 EC No 200-666-4	Shall not be placed on the market, or used, as substance or in mixtures, where the substance or mixture is intended for the manufacturing or processing of non-ferrous metals.
43. Azocolourants and Azodyes	<p>1. Azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in Appendix 8, in detectable concentrations, i.e. above 30 mg/kg (0,003 % by weight) in the articles or in the dyed parts thereof, according to the testing methods listed in Appendix 10, shall not be used, in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity, such as:</p> <ul style="list-style-type: none"> — clothing, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items, sleeping bags, — footwear, gloves, wristwatch straps, handbags, purses/wallets, briefcases, chair covers, purses worn round the neck, — textile or leather toys and toys which include textile or leather garments, — yarn and fabrics intended for use by the final consumer. <p>2. Furthermore, the textile and leather articles referred to in paragraph 1 shall not be placed on the market unless they conform to the requirements set out in that paragraph.</p> <p>3. Azodyes, which are contained in Appendix 9, 'List of azodyes' shall not be placed on the market, or used, as substances, or in mixtures in concentrations greater than 0,1 % by weight, where the substance or the mixture is intended for colouring textile and leather articles.</p>
45. Diphenylether, octabromo derivative C12H2Br8O	<p>1. Shall not be placed on the market, or used:</p> <ul style="list-style-type: none"> — as a substance, — as a constituent of other substances, or in mixtures, in concentrations greater than 0,1 % by weight.



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	<p>2. Articles shall not be placed on the market if they, or flame-retardant parts thereof, contain this substance in concentrations greater than 0,1 % by weight.</p> <p>3. By way of derogation, paragraph 2 shall not apply:</p> <ul style="list-style-type: none"> — to articles that were in use in the Community before 15 August 2004, — to electrical and electronic equipment within the scope of Directive 2002/95/EC.
<p>46.</p> <p>(a) Nonylphenol $C_6H_4(OH)C_9H_{19}$</p> <p>(b) Nonylphenol ethoxylates $(C_2H_4O)_n C_{15}H_{24}O$</p>	<p>Shall not be placed on the market, or used, as substances or in mixtures in concentrations equal to or greater than 0,1 % by weight for the following purposes:</p> <p>(1) industrial and institutional cleaning except:</p> <ul style="list-style-type: none"> — controlled closed dry cleaning systems where the washing liquid is recycled or incinerated, — cleaning systems with special treatment where the washing liquid is recycled or incinerated. <p>(2) domestic cleaning;</p> <p>(3) textiles and leather processing except:</p> <ul style="list-style-type: none"> — processing with no release into waste water, — systems with special treatment where the process water is pre-treated to remove the organic fraction completely prior to biological waste water treatment (degreasing of sheepskin); <p>(4) emulsifier in agricultural teat dips;</p> <p>(5) metal working except: uses in controlled closed systems where the washing liquid is recycled or incinerated;</p> <p>(6) manufacturing of pulp and paper;</p> <p>(7) cosmetic products;</p> <p>(8) other personal care products except: spermicides;</p> <p>(9) co-formulants in pesticides and biocides. However national authorisations for pesticides or biocidal products containing nonylphenol ethoxylates as co-formulant, granted before 17 July 2003, shall not be affected by this restriction until their date of expiry.</p>
<p>46a. Nonylphenol ethoxylates (NPE) $(C_2H_4O)_n C_{15}H_{24}O$</p>	<p>1. Shall not be placed on the market after 3 February 2021 in textile articles which can reasonably be expected to be washed in water during their normal lifecycle, in concentrations equal to or greater than 0,01 % by weight of that textile article or of each part of the textile article.</p> <p>2. Paragraph 1 shall not apply to the placing on the market of second-hand textile articles or of new textile articles produced, without the use of NPE, exclusively from recycled textiles.</p> <p>3. For the purposes of paragraphs 1 and 2, 'textile article' means any unfinished, semi-finished or finished product which is composed of at least 80 % textile fibres by weight, or any other product that contains a part</p>



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	which is composed of at least 80 % textile fibres by weight, including products such as clothing, accessories, interior textiles, fibres, yarn, fabrics and knitted panels.
47. Chromium VI compounds	<p>1. Cement and cement-containing mixtures shall not be placed on the market, or used, if they contain, when hydrated, more than 2 mg/kg (0,0002 %) soluble chromium VI of the total dry weight of the cement.</p> <p>2. If reducing agents are used, then without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of cement or cement-containing mixtures is visibly, legibly and indelibly marked with information on the packing date, as well as on the storage conditions and the storage period appropriate to maintaining the activity of the reducing agent and to keeping the content of soluble chromium VI below the limit indicated in paragraph 1.</p> <p>3. By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for, and use in, controlled closed and totally automated processes in which cement and cement-containing mixtures are handled solely by machines and in which there is no possibility of contact with the skin.</p> <p>4. The standard adopted by the European Committee for Standardization (CEN) for testing the water-soluble chromium (VI) content of cement and cement-containing mixtures shall be used as the test method for demonstrating conformity with paragraph 1.</p> <p>5. Leather articles coming into contact with the skin shall not be placed on the market where they contain chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of the leather.</p> <p>6. Articles containing leather parts coming into contact with the skin shall not be placed on the market where any of those leather parts contains chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of that leather part.</p> <p>7. Paragraphs 5 and 6 shall not apply to the placing on the market of second-hand articles which were in end-use in the Union before 1 May 2015.</p>
48. Toluene CAS No 108-88-3 EC No 203-625-9	Shall not be placed on the market, or used, as a substance or in mixtures in a concentration equal to or greater than 0,1 % by weight where the substance or mixture is used in adhesives or spray paints intended for supply to the general public.
49. Trichlorobenzene CAS No 120-82-1 EC No 204-428-0	Shall not be placed on the market, or used, as a substance or in mixtures in a concentration equal to or greater than 0,1 % by weight for any use except: — as an intermediate of synthesis, or,



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	<p>— as a process solvent in closed chemical applications for chlorination reactions, or,</p> <p>— in the manufacture of 1,3,5-triamino — 2,4,6-trinitrobenzene (TATB).</p>
<p>50. Polycyclic-aromatic hydrocarbons (PAH)</p> <p>(a) Benzo[a]pyrene (BaP) CAS No 50-32-8</p> <p>(b) Benzo[e]pyrene (BeP) CAS No 192-97-2</p> <p>(c) Benzo[a]anthracene (BaA) CAS No 56-55-3</p> <p>(d) Chrysen (CHR) CAS No 218-01-9</p> <p>(e) Benzo[b]fluoranthene (BbFA) CAS No 205-99-2</p> <p>(f) Benzo[j]fluoranthene (BjFA) CAS No 205-82-3</p> <p>(g) Benzo[k]fluoranthene (BkFA) CAS No 207-08-9</p> <p>(h) Dibenzo[a,h]anthracene (DBAhA) CAS No 53-70-3</p>	<p>1. From 1 January 2010, extender oils shall not be placed on the market, or used for the production of tyres or parts of tyres if they contain:</p> <ul style="list-style-type: none"> — more than 1 mg/kg (0,0001 % by weight) BaP, or, — more than 10 mg/kg (0,001 % by weight) of the sum of all listed PAHs. <p>The standard EN 16143:2013 (Petroleum products — Determination of content of Benzo(a)pyrene (BaP) and selected polycyclic aromatic hydrocarbons (PAH) in extender oils — Procedure using double LC cleaning and GC/MS analysis) shall be used as the test method for demonstrating conformity with the limits referred to in the first subparagraph.</p> <p>Until 23 September 2016, the limits referred to in the first subparagraph may be regarded as kept, if the polycyclic aromatics (PCA) extract is less than 3 % by weight as measured by the Institute of Petroleum standard IP 346:1998 (Determination of PCA in unused lubricating base oils and asphaltene free petroleum fractions — Dimethyl sulphoxide extraction refractive index method), provided that compliance with the limits of BaP and of the listed PAHs, as well as the correlation of the measured values with the PCA extract, is measured by the manufacturer or importer every six months or after each major operational change, whichever is earlier.</p> <p>2. Furthermore, tyres and treads for retreading manufactured after 1 January 2010 shall not be placed on the market if they contain extender oils exceeding the limits indicated in paragraph 1.</p> <p>These limits shall be regarded as kept, if the vulcanised rubber compounds do not exceed the limit of 0,35 % Bay protons as measured and calculated by ISO 21461 (Rubber vulcanised — Determination of aromaticity of oil in vulcanised rubber compounds).</p> <p>3. By way of derogation, paragraph 2 shall not apply to retreaded tyres if their tread does not contain extender oils exceeding the limits referred to in paragraph 1.</p> <p>4. For the purpose of this entry 'tyres' shall mean tyres for vehicles covered by:</p> <ul style="list-style-type: none"> — Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, — Directive 2003/37/EC of the European Parliament and of the Council of 26 May 2003 on type-approval of agricultural or forestry tractors, their trailers and interchangeable towed machinery, together with their systems, components and separate technical units, and — Directive 2002/24/EC of the European Parliament and of the Council



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of 18 March 2002 relating to the type-approval of two or three-wheel motor vehicles and repealing Council Directive 92/61/EEC.

5. Articles shall not be placed on the market for supply to the general public, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 1 mg/kg (0,0001 % by weight of this component) of any of the listed PAHs.

Such articles include amongst others:

- sport equipment such as bicycles, golf clubs, racquets
- household utensils, trolleys, walking frames
- tools for domestic use
- clothing, footwear, gloves and sportswear
- watch-straps, wrist-bands, masks, head-bands

6. Toys, including activity toys, and childcare articles, shall not be placed on the market, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 0,5 mg/kg (0,00005 % by weight of this component) of any of the listed PAHs.

7. By way of derogation from paragraphs 5 and 6, these paragraphs shall not apply to articles placed on the market for the first time before 27 December 2015.

8. By 27 December 2017, the Commission shall review the limit values in paragraphs 5 and 6 in the light of new scientific information, including migration of PAHs from the articles referred to therein, and information on alternative raw materials and, if appropriate, modify these paragraphs accordingly.

9. Granules or mulches shall not be placed on the market for use as infill material in synthetic turf pitches or in loose form on playgrounds or in sport applications if they contain more than 20 mg/kg (0,002 % by weight) of the sum of all listed PAHs.

10. Granules or mulches shall not be used as infill material in synthetic turf pitches or in loose form on playgrounds or in sport applications if they contain more than 20 mg/kg (0,002 % by weight) of the sum of all listed PAHs.

11. Granules or mulches placed on the market for use as infill material in synthetic turf pitches or in loose form on playgrounds or in sport applications shall be marked with a unique identification number of the batch.

12. Paragraphs 9 to 11 shall apply from 10 August 2022.

13. Granules or mulches that are in use in the Union on 9 August 2022 as infill material in synthetic turf pitches or in loose form on playgrounds or



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	<p>in sport applications may remain in place and continue to be used there for the same purpose.</p> <p>14. For the purposes of paragraphs 9 to 13:</p> <p>a. “granules” are mixtures that appear as solid particles in the size range from 1 to 4 mm, which are made from rubber or other vulcanised or polymeric material of recycled or virgin origin, or obtained from a natural source;</p> <p>b. “mulches” are mixtures that appear as flake-shaped solid particles in the size range from 4 to 130 mm length and 10 to 15 mm width, which are made from rubber or other vulcanised or polymeric material of recycled or virgin origin, or obtained from a natural source;</p> <p>c. “infill material in synthetic turf pitches” consists of granules used in synthetic turf pitches to improve the sport technical performance characteristics of the turf system;</p> <p>d. “use in loose form on playgrounds or in sport applications” is any use of granules or mulches in loose form on playgrounds or for sport purposes other than as infill material in synthetic turf pitches.’</p>
<p>51.</p> <p>Bis(2-ethylhexyl) phthalate (DEHP)</p> <p>CAS No.: 117-81-7</p> <p>EC No.: 204-211-0</p> <p>Dibutyl phthalate (DBP)</p> <p>CAS No.: 84-74-2</p> <p>EC No.: 201-557-4</p> <p>Benzyl butyl phthalate (BBP)</p> <p>CAS No.: 85-68-7</p> <p>EC No.: 201-622-7</p> <p>Diisobutyl phthalate (DIBP)</p> <p>CAS No.: 84-69-5</p> <p>EC No.: 201-553-2</p>	<p>1. Shall not be used as substances or in mixtures, individually or in any combination of the phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material, in toys and childcare articles.</p> <p>2. Shall not be placed on the market in toys or childcare articles, individually or in any combination of the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material.</p> <p>In addition, DIBP shall not be placed on the market after 7 July 2020 in toys or childcare articles, individually or in any combination with the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material.</p> <p>3. Shall not be placed on the market after 7 July 2020 in articles, individually or in any combination of the phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material in the article.</p> <p>4. Paragraph 3 shall not apply to:</p> <p>(a) articles exclusively for industrial or agricultural use, or for use exclusively in the open air, provided that no plasticised material comes into contact with human mucous membranes or into prolonged contact with human skin;</p> <p>(b) aircraft, placed on the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those aircraft, where those articles are essential for the safety and airworthiness of the aircraft;</p> <p>(c) motor vehicles within the scope of Directive 2007/46/EC, placed on</p>



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	<p>the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those vehicles, where the vehicles cannot function as intended without those articles;</p> <p>(d) articles placed on the market before 7 July 2020;</p> <p>(e) measuring devices for laboratory use, or parts thereof;</p> <p>(f) materials and articles intended to come into contact with food within the scope of Regulation (EC) No 1935/2004 or Commission Regulation (EU) No 10/2011;</p> <p>(g) medical devices within the scope of Directives 90/385/EEC, 93/42/EEC or 98/79/EC, or parts thereof;</p> <p>(h) electrical and electronic equipment within the scope of Directive 2011/65/EU;</p> <p>(i) the immediate packaging of medicinal products within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC;</p> <p>(j) toys and childcare articles covered by paragraphs 1 or 2.</p> <p>5. For the purposes of paragraphs 1, 2, 3 and 4(a),</p> <p>(a) 'plasticised material' means any of the following homogeneous materials:</p> <ul style="list-style-type: none"> — polyvinyl chloride (PVC), polyvinylidene chloride (PVDC), polyvinyl acetate (PVA), polyurethanes, — any other polymer (including, inter alia, polymer foams and rubber material) except silicone rubber and natural latex coatings, — surface coatings, non-slip coatings, finishes, decals, printed designs, — adhesives, sealants, paints and inks. <p>(b) 'prolonged contact with human skin' means continuous contact of more than 10 minutes duration or intermittent contact over a period of 30 minutes, per day.</p> <p>(c) 'childcare article' shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.</p> <p>6. For the purposes of paragraph 4(b), 'aircraft' means one of the following:</p> <p>(a) a civil aircraft produced in accordance with a type certificate issued under Regulation (EC) No 216/2008 or with a design approval issued under the national regulations of a contracting State of the International Civil Aviation Organisation (ICAO), or for which a certificate of airworthiness has been issued by an ICAO contracting State under Annex 8 to the Convention on International Civil Aviation, signed on December 7, 1944, in Chicago;</p> <p>(b) a military aircraft.</p>
52. The following phthalates (or other CAS- and EC numbers	<p>1. Shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and</p>



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<p>covering the substance):</p> <p>(a) Di-‘isononyl’ phthalate (DINP) CAS No 28553-12-0 and 68515-48-0 EC No 249-079-5 and 271-090-9</p> <p>(b) Di-‘isodecyl’ phthalate (DIDP) CAS No 26761-40-0 and 68515-49-1 EC No 247-977-1 and 271-091-4</p> <p>(c) Di-n-octyl phthalate (DNOP) CAS No 117-84-0 EC No 204-214-7</p>	<p>childcare articles which can be placed in the mouth by children.</p> <p>2. Such toys and childcare articles containing these phthalates in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market.</p> <p>4. For the purpose of this entry ‘childcare article’ shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.</p>
<p>54.</p> <p>2-(2-methoxyethoxy)ethanol (DEGME) CAS No 111-77-3 EC No 203-906-6</p>	<p>Shall not be placed on the market after 27 June 2010, for supply to the general public, as a constituent of paints, paint strippers, cleaning agents, self-shining emulsions or floor sealants in concentrations equal to or greater than 0,1 % by weight.</p>
<p>55. 2-(2-butoxyethoxy)ethanol (DEGBE) CAS No 112-34-5 EC No 203-961-6</p>	<p>1. Shall not be placed on the market for the first time after 27 June 2010, for supply to the general public, as a constituent of spray paints or spray cleaners in aerosol dispensers in concentrations equal to or greater than 3 % by weight.</p> <p>2. Spray paints and spray cleaners in aerosol dispensers containing DEGBE and not conforming to paragraph 1 shall not be placed on the market for supply to the general public after 27 December 2010.</p> <p>3. Without prejudice to other Community legislation concerning the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that paints other than spray paints containing DEGBE in concentrations equal to or greater than 3 % by weight of that are placed on the market for supply to the general public are visibly, legibly and indelibly marked by 27 December 2010 as follows:</p> <p>‘Do not use in paint spraying equipment’.</p>
<p>56. Methylenediphenyl diisocyanate (MDI) CAS No 26447-40-5 EC No 247-714-0</p>	<p>1. Shall not be placed on the market after 27 December 2010, as a constituent of mixtures in concentrations equal to or greater than 0,1 % by weight of MDI for supply to the general public, unless suppliers shall ensure before the placing on the market that the packaging:</p>



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<p>including the following specific isomers:</p> <p>(a) 4,4'-Methylenediphenyl diisocyanate: CAS No 101-68-8 EC No 202-966-0;</p> <p>(b) 2,4'-Methylenediphenyl diisocyanate: CAS No 5873-54-1 EC No 227-534-9;</p> <p>(c) 2,2'-Methylenediphenyl diisocyanate: CAS No 2536-05-2 EC No 219-799-4</p>	<p>(a) contains protective gloves which comply with the requirements of Council Directive 89/686/EEC;</p> <p>(b) is marked visibly, legibly and indelibly as follows, and without prejudice to other Community legislation concerning the classification, packaging and labelling of substances and mixtures:</p> <ul style="list-style-type: none"> — Persons already sensitised to diisocyanates may develop allergic reactions when using this product. — Persons suffering from asthma, eczema or skin problems should avoid contact, including dermal contact, with this product. — This product should not be used under conditions of poor ventilation unless a protective mask with an appropriate gas filter (i.e. type A1 according to standard EN 14387) is used. <p>2. By way of derogation, paragraph 1(a) shall not apply to hot melt adhesives.</p>
<p>57. Cyclohexane CAS No 110-82-7 EC No 203-806-2</p>	<p>1. Shall not be placed on the market for the first time after 27 June 2010, for supply to the general public, as a constituent of neoprene-based contact adhesives in concentrations equal to or greater than 0,1 % by weight in package sizes greater than 350 g.</p> <p>2. Neoprene-based contact adhesives containing cyclohexane and not conforming to paragraph 1 shall not be placed on the market for supply to the general public after 27 December 2010.</p> <p>3. Without prejudice to other Community legislation concerning the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that neoprene-based contact adhesives containing cyclohexane in concentrations equal to or greater than 0,1 % by weight that are placed on the market for supply to the general public after 27 December 2010 are visibly, legibly and indelibly marked as follows:</p> <ul style="list-style-type: none"> — This product is not to be used under conditions of poor ventilation. — This product is not to be used for carpet laying.
<p>58. Ammonium nitrate (AN) CAS No 6484-52-2 EC No 229-347-8</p>	<p>1. Shall not be placed on the market for the first time after 27 June 2010 as a substance, or in mixtures that contain more than 28 % by weight of nitrogen in relation to ammonium nitrate, for use as a solid fertiliser, straight or compound, unless the fertiliser complies with the technical provisions for ammonium nitrate fertilisers of high nitrogen content set out in Annex III to Regulation (EC) No 2003/2003 of the European Parliament and of the Council.</p>
<p>59. Dichloromethane CAS No 75-09-2 EC No: 200-838-9</p>	<p>1. Paint strippers containing dichloromethane in a concentration equal to or greater than 0,1 % by weight shall not be:</p> <p>(a) placed on the market for the first time for supply to the general public or to professionals after 6 December 2010;</p> <p>(b) placed on the market for supply to the general public or to professionals after 6 December 2011;</p>



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(c) used by professionals after 6 June 2012.

For the purposes of this entry:

- (i) 'professional' means any natural or legal person, including workers and self-employed workers undertaking paint stripping in the course of their professional activity outside an industrial installation;
- (ii) 'industrial installation' means a facility used for paint stripping activities.

2. By way of derogation from paragraph 1, Member States may allow on their territories and for certain activities the use, by specifically trained professionals, of paint strippers containing dichloromethane and may allow the placing on the market of such paint strippers for supply to those professionals.

Member States making use of this derogation shall define appropriate provisions for the protection of the health and safety of those professionals using paint strippers containing dichloromethane and shall inform the Commission thereof.

Those provisions shall include a requirement that a professional shall hold a certificate that is accepted by the Member State in which that professional operates, or provide other documentary evidence to that effect, or be otherwise approved by that Member State, so as to demonstrate proper training and competence to safely use paint strippers containing dichloromethane.

The Commission shall prepare a list of the Member States which have made use of the derogation in this paragraph and make it publicly available over the Internet.

3. A professional benefiting from the derogation referred to in paragraph 2 shall operate only in Member States which have made use of that derogation. The training referred to in paragraph 2 shall cover as a minimum:

- (a) awareness, evaluation and management of risks to health, including information on existing substitutes or processes, which under their conditions of use are less hazardous to the health and safety of workers;
- (b) use of adequate ventilation;
- (c) use of appropriate personal protective equipment that complies with Directive 89/686/EEC.

Employers and self-employed workers shall preferably replace dichloromethane with a chemical agent or process which, under its conditions of use, presents no risk, or a lower risk, to the health and safety of workers.

Professional shall apply all relevant safety measures in practice, including the use of personal protective equipment.

4. Without prejudice to other Community legislation on workers protection, paint strippers containing dichloromethane in concentrations



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	<p>equal to or greater than 0,1 % by weight may be used in industrial installations only if the following minimum conditions are met:</p> <p>(a) effective ventilation in all processing areas, in particular for the wet processing and the drying of stripped articles: local exhaust ventilation at strip tanks supplemented by forced ventilation in those areas, so as to minimise exposure and to ensure compliance, where technically feasible, with relevant occupational exposure limits;</p> <p>(b) measures to minimise evaporation from strip tanks comprising: lids for covering strip tanks except during loading and unloading; suitable loading and unloading arrangements for strip tanks; and wash tanks with water or brine to remove excess solvent after unloading;</p> <p>(c) measures for the safe handling of dichloromethane in strip tanks comprising: pumps and pipework for transferring paint stripper to and from strip tanks; and suitable arrangements for safe cleaning of tanks and removal of sludge;</p> <p>(d) personal protective equipment that complies with Directive 89/686/EEC comprising: suitable protective gloves, safety goggles and protective clothing; and appropriate respiratory protective equipment where compliance with relevant occupational exposure limits cannot be otherwise achieved;</p> <p>(e) adequate information, instruction and training for operators in the use of such equipment.</p> <p>5. Without prejudice to other Community provisions concerning the classification, labelling and packaging of substances and mixtures, by 6 December 2011 paint strippers containing dichloromethane in a concentration equal to or greater than 0,1 % by weight shall be visibly, legibly and indelibly marked as follows: 'Restricted to industrial use and to professionals approved in certain EU Member States — verify where use is allowed.'</p>
60. Acrylamide CAS No 79-06-1	Shall not be placed on the market or used as a substance or constituent of mixtures in a concentration, equal to or greater than 0,1 % by weight for grouting applications after 5 November 2012.
61. Dimethylfumarate (DMF) CAS No 624-49-7 EC 210-849-0	Shall not be used in articles or any parts thereof in concentrations greater than 0,1 mg/kg. Articles or any parts thereof containing DMF in concentrations greater than 0,1 mg/kg shall not be placed on the market.
62. (a) Phenylmercury acetate EC No: 200-532-5 CAS No: 62-38-4 (b) Phenylmercury propionate EC No: 203-094-3	<p>1. Shall not be manufactured, placed on the market or used as substances or in mixtures after 10 October 2017 if the concentration of mercury in the mixtures is equal to or greater than 0,01 % by weight.</p> <p>2. Articles or any parts thereof containing one or more of these substances shall not be placed on the market after 10 October 2017 if the concentration of mercury in the articles or any part thereof is equal to or greater than 0,01 % by weight.</p>



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<p>CAS No: 103-27-5</p> <p>(c) Phenylmercury 2-ethylhexanoate EC No: 236-326-7 CAS No: 13302-00-6</p> <p>(d) Phenylmercury octanoate EC No: - CAS No: 13864-38-5</p> <p>(e) Phenylmercury neodecanoate EC No: 247-783-7 CAS No: 26545-49-3</p>	
<p>63. Lead CAS No 7439-92-1 EC No 231-100-4 and its compounds</p>	<ol style="list-style-type: none"> 1. Shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0,05 % by weight. 2. For the purposes of paragraph 1: <ol style="list-style-type: none"> (i) 'jewellery articles' shall include jewellery and imitation jewellery articles and hair accessories, including: <ol style="list-style-type: none"> (a) bracelets, necklaces and rings; (b) piercing jewellery; (c) wrist watches and wrist-wear; (d) brooches and cufflinks; (ii) 'any individual part' shall include the materials from which the jewellery is made, as well as the individual components of the jewellery articles. 3. Paragraph 1 shall also apply to individual parts when placed on the market or used for jewellery-making. 4. By way of derogation, paragraph 1 shall not apply to: <ol style="list-style-type: none"> (a) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC; (b) internal components of watch timepieces inaccessible to consumers; (c) non-synthetic or reconstructed precious and semiprecious stones (CN code 7103 , as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its compounds or mixtures containing these substances; (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C.



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5. By way of derogation, paragraph 1 shall not apply to jewellery articles placed on the market for the first time before 9 October 2013 and jewellery articles produced before 10 December 1961.

6. By 9 October 2017, the Commission shall re-evaluate paragraphs 1 to 5 of this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 1 and, if appropriate, modify this entry accordingly.

7. Shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0,05 % by weight, and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children.

That limit shall not apply where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0,05 $\mu\text{g}/\text{cm}^2$ per hour (equivalent to 0,05 $\mu\text{g}/\text{g}/\text{h}$), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article.

For the purposes of this paragraph, it is considered that an article or accessible part of an article may be placed in the mouth by children if it is smaller than 5 cm in one dimension or has a detachable or protruding part of that size.

8. By way of derogation, paragraph 7 shall not apply to:

- (a) jewellery articles covered by paragraph 1;
- (b) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Directive 69/493/EEC;
- (c) non-synthetic or reconstructed precious and semi-precious stones (CN code 7103 as established by Regulation (EEC) No 2658/87) unless they have been treated with lead or its compounds or mixtures containing these substances;
- (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of mineral melted at a temperature of at least 500 °C;
- (e) keys and locks, including padlocks;
- (f) musical instruments;
- (g) articles and parts of articles comprising brass alloys, if the concentration of lead (expressed as metal) in the brass alloy does not



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- exceed 0,5 % by weight;
- (h) the tips of writing instruments;
- (i) religious articles;
- (j) portable zinc-carbon batteries and button cell batteries;
- (k) articles within the scope of:
 - (i) Directive 94/62/EC;
 - (ii) Regulation (EC) No 1935/2004;
 - (iii) Directive 2009/48/EC of the European Parliament and of the Council;
 - (iv) Directive 2011/65/EU of the European Parliament and of the Council.

9. By 1 July 2019, the Commission shall re-evaluate paragraphs 7 and 8(e), (f), (i) and (j) of this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 7, including the requirement on coating integrity, and, if appropriate, modify this entry accordingly.

10. By way of derogation paragraph 7 shall not apply to articles placed on the market for the first time before 1 June 2016.

11. Doing either of the following acts after 15 February 2023 in or within 100 metres of wetlands is prohibited:

- (a) discharging gunshot containing a concentration of lead (expressed as metal) equal to or greater than 1 % by weight;
- (b) carrying any such gunshot where this occurs while out wetland shooting or as part of going wetland shooting.

For the purposes of the first subparagraph:

- (a) 'within 100 metres of wetlands' means within 100 metres outward from any outer boundary point of a wetland;
- (b) 'wetland shooting' means shooting in or within 100 metres of wetlands;
- (c) if a person is found carrying gunshot in or within 100 metres of wetlands while out shooting or as part of going shooting, the shooting concerned shall be presumed to be wetland shooting unless that person can demonstrate that it was some other type of shooting.

The restriction laid down in the first subparagraph shall not apply in a Member State if that Member State notifies the Commission in accordance with paragraph 12 that it intends to make use of the option granted by that paragraph.

12. If at least 20 % in total of the territory, excluding the territorial waters, of a Member State are wetlands, that Member State may, in place of the restriction laid down in the first subparagraph of paragraph 11, prohibit the following acts throughout the whole of its territory from 15 February 2024:



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	<p>(a) the placing on the market of gunshot containing a concentration of lead (expressed as metal) equal to or greater than 1 % by weight;</p> <p>(b) the discharging of any such gunshot;</p> <p>(c) carrying any such gunshot while out shooting or as part of going shooting.</p> <p>Any Member State intending to make use of the option granted by the first subparagraph shall notify the Commission of this intention by 15 August 2021. The Member State shall communicate the text of the national measures adopted by it to the Commission without delay and in any event by 15 August 2023. The Commission shall make publicly available without delay any such notices of intention and texts of national measures received by it.</p> <p>13. For the purposes of paragraphs 11 and 12:</p> <p>(a) 'wetlands' means areas of marsh, fen, peatland or water, whether natural or artificial, permanent or temporary, with water that is static or flowing, fresh, brackish or salt, including areas of marine water the depth of which at low tide does not exceed 6 metres;</p> <p>(b) 'gunshot' means pellets used or intended for use in a single charge or cartridge in a shotgun;</p> <p>(c) 'shotgun' means a smooth-bore gun, excluding airguns;</p> <p>(d) 'shooting' means any shooting with a shotgun;</p> <p>(e) 'carrying' means any carrying on the person or carrying or transporting by any other means;</p> <p>(f) in determining whether a person found with gunshot is carrying gunshot 'as part of going shooting':</p> <p>(i) regard shall be had to all the circumstances of the case;</p> <p>(ii) the person found with the gunshot need not necessarily be the same person as the person shooting.</p> <p>14. Member States may maintain national provisions for protection of the environment or human health in force on 15 February 2021 and restricting lead in gunshot more severely than provided for in paragraph 11.</p> <p>The Member State shall communicate the text of those national provisions to the Commission without delay. The Commission shall make publicly available without delay any such texts of national provisions received by it.</p>
64. 1,4-dichlorobenzene CAS No 106-46-7 EC No 203-400-5	Shall not be placed on the market or used, as a substance or as a constituent of mixtures in a concentration equal to or greater than 1 % by weight, where the substance or the mixture is placed on the market for use or used as an air freshener or deodoriser in toilets, homes, offices or other indoor public areas.
65. Inorganic ammonium salts	1. Shall not be placed on the market, or used, in cellulose insulation



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	<p>mixtures or cellulose insulation articles after 14 July 2018 unless the emission of ammonia from those mixtures or articles results in a concentration of less than 3 ppm by volume (2,12 mg/m³) under the test conditions specified in paragraph 4.</p> <p>A supplier of a cellulose insulation mixture containing inorganic ammonium salts shall inform the recipient or consumer of the maximum permissible loading rate of the cellulose insulation mixture, expressed in thickness and density.</p> <p>A downstream user of a cellulose insulation mixture containing inorganic ammonium salts shall ensure that the maximum permissible loading rate communicated by the supplier is not exceeded.</p> <p>2. By way of derogation, paragraph 1 shall not apply to placing on the market of cellulose insulation mixtures intended to be used solely for the production of cellulose insulation articles, or to the use of those mixtures in the production of cellulose insulation articles.</p> <p>3. In the case of a Member State that, on 14 July 2016, has national provisional measures in place that have been authorised by the Commission pursuant to Article 129(2)(a), the provisions of paragraphs 1 and 2 shall apply from that date.</p> <p>4. Compliance with the emission limit specified in the first subparagraph of paragraph 1 shall be demonstrated in accordance with Technical Specification CEN/TS 16516, adapted as follows:</p> <p>(a) the duration of the test shall be at least 14 days instead of 28 days;</p> <p>(b) the ammonia gas emission shall be measured at least once per day throughout the test;</p> <p>(c) the emission limit shall not be reached or exceeded in any measurement taken during the test;</p> <p>(d) the relative humidity shall be 90 % instead of 50 %;</p> <p>(e) an appropriate method to measure the ammonia gas emission shall be used;</p> <p>(f) the loading rate, expressed in thickness and density, shall be recorded during the sampling of the cellulose insulation mixtures or articles to be tested.</p>
66. Bisphenol A CAS No 80-05-7 EC No 201-245-8	Shall not be placed on the market in thermal paper in a concentration equal to or greater than 0,02 % by weight after 2 January 2020.
68. Linear and branched perfluorocarboxylic acids of the formula $C_nF_{2n+1}-C(=O)OH$ where n=8, 9, 10, 11, 12, or 13 (C9-C14 PFCAs),	<p>1. Shall not be manufactured, or placed on the market as substances on their own from 25 February 2023.</p> <p>2. Shall not, from 25 February 2023, be used in, or placed on the market in:</p> <p>(a) another substance, as a constituent;</p>



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including their salts, and any combinations thereof;

Any C9-C14 PFCA-related substance having a perfluoro group with the formula $C_nF_{2n+1}-$ directly attached to another carbon atom, where $n=8, 9, 10, 11, 12$, or 13 , including their salts and any combinations thereof;

Any C9-C14 PFCA-related substance having a perfluoro group with the formula $C_nF_{2n+1}-$ that it is not directly attached to another carbon atom, where $n=9, 10, 11, 12, 13$ or 14 as one of the structural elements, including their salts and any combinations thereof.

The following substances are excluded from this designation

- $C_nF_{2n+1}-X$, where $X= F, Cl$, or Br

where $n=9, 10, 11, 12, 13$ or 14 , including any combinations thereof;

- $C_nF_{2n+1}-C(=O)OX'$ where $n>13$ and X' =any group, including salts.

(b) a mixture;

(c) an article,

except if the concentration in the substance, the mixture, or the article is below 25 ppb for the sum of C9-C14 PFCAs and their salts or 260 ppb for the sum of C9-C14 PFCA-related substances.

3. By way of derogation to paragraph 2, the concentration limit shall be 10 ppm for the sum of C9-C14 PFCAs, their salts and C9-C14 PFCA related substances, where they are present in a substance to be used as a transported isolated intermediate, provided that the conditions in points (a) to (f) of Article 18(4) of this Regulation are met for the manufacturing of fluorochemicals with a perfluoro carbon chain length equal to or shorter than 6 atoms. The Commission shall review this limit no later than 25 August 2023.

4. Paragraph 2 shall apply from 4 July 2023 to :

- (i) textiles for oil- and water-repellency for the protection of workers from dangerous liquids that comprise risks to their health and safety;
- (ii) the manufacture of polytetrafluoroethylene (PTFE) and polyvinylidene fluoride (PVDF) for the production of :
 - high performance, corrosion resistant gas filter membranes, water filter membranes and membranes for medical textiles;
 - industrial waste heat exchanger equipment;
 - industrial sealants capable of preventing leakage of volatile organic compounds and PM 2.5 particulates.

5. By way of derogation to paragraph 2, the use of C9-C14 PFCAs, their salts and C9-C14 PFCA-related substances shall be allowed until 4 July 2025 for:

- (i) photolithography or etch processes in semiconductor manufacturing;
- (ii) photographic coatings applied to films;
- (iii) invasive and implantable medical devices;
- (iv) fire-fighting foam for liquid fuel vapour suppression and liquid fuel fire (Class B fires) already installed in systems, including both mobile and fixed systems, subject to the following conditions:
 - fire-fighting foam that contains or may contain C9-C14 PFCAs, their salts and C9-C14 PFCA-related substances shall not be used for training;
 - fire-fighting foam that contains or may contain C9-C14 PFCAs, their salts and C9-C14 PFCA-related substances shall not be used for



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	<p>testing unless all releases are contained;</p> <ul style="list-style-type: none"> - from 1 January 2023, uses of fire-fighting foam that contains or may contain C9-C14 PFCAs, their salts and C9-C14 PFCA-related substances shall only be allowed to sites where all releases can be contained; - fire-fighting foam stockpiles that contain or may contain C9-C14 PFCAs, their salts and C9-C14 PFCA-related substances shall be managed in accordance with Article 5 of Regulation (EU) 2019/1021. <p>6. Paragraph 2(c) shall not apply to articles placed on the market before 25 February 2023.</p> <p>7. Paragraph 2 shall not apply to the can coating for pressurised metered-dose inhalers until 25 August 2028.</p> <p>8. Paragraph 2 (c) shall apply from 31 December 2023 to:</p> <ul style="list-style-type: none"> (a) semiconductors on their own; (b) semiconductors incorporated in semi-finished and finished electronic equipment. <p>9. Paragraph 2(c) shall apply from 31 December 2030 to semiconductors used in spare or replacement parts for finished electronic equipment placed on the market before 31 December 2023.</p> <p>10. Until 25 August 2024, the concentration limit referred to in paragraph 2 shall be 2 000 ppb for the sum of C9-C14 PFCAs in fluoroplastics and fluoroelastomers that contain perfluoroalkoxy groups. From 25 August 2024, the concentration limit shall be 100 ppb for the sum of C9-C14 PFCAs, in fluoroplastics and fluoroelastomers that contain perfluoroalkoxy groups. All emissions of C9-C14 PFCAs during the manufacture and use of fluoroplastics and fluoroelastomers that contain perfluoroalkoxy groups shall be avoided and, if not possible, reduced as far as technically and practically possible. This derogation shall not apply to articles referred to in paragraph 2(c). The Commission shall review this derogation no later than 25 August 2024.</p> <p>11. The concentration limit referred to in paragraph 2 shall be 1 000 ppb for the sum of C9-C14 PFCAs, where these are present in PTFE micro powders produced by ionising irradiation or by thermal degradation, as well as in mixtures and articles for industrial and professional uses</p>
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	<p>containing PTFE micro powders. All emissions of C9-C14 PFCAs during the manufacture and use of PTFE micro powders shall be avoided and, if not possible, reduced as far as technically and practically possible. The Commission shall review this derogation no later than 25 August 2024.</p> <p>12. For the purposes of this entry, C9-C14 PFCA-related substances are substances that, based on their molecular structure, are considered to have the potential to degrade or be transformed to C9-C14 PFCAs.</p>
<p>69. Methanol CAS No 67-56-1 EC No 200-659-6</p>	<p>Shall not be placed on the market to the general public after 9 May 2019 in windscreen washing or defrosting fluids, in a concentration equal to or greater than 0,6 % by weight.</p>
<p>70. Octamethylcyclotetrasiloxane (D4) CAS No 556-67-2 EC No 209-136-7</p> <p>Decamethylcyclopentasiloxane (D5) CAS No 541-02-6 EC No 208-764-9</p>	<p>1. Shall not be placed on the market in wash-off cosmetic products in a concentration equal to or greater than 0,1 % by weight of either substance, after 31 January 2020.</p> <p>2. For the purposes of this entry, 'wash-off cosmetic products' means cosmetic products as defined in Article 2(1)(a) of Regulation (EC) No 1223/2009 that, under normal conditions of use, are washed off with water after application.</p>
<p>71. 1-methyl-2-pyrrolidone (NMP) CAS No 872-50-4 EC No 212-828-1</p>	<p>1. Shall not be placed on the market as a substance on its own or in mixtures in a concentration equal to or greater than 0,3 % after 9 May 2020 unless manufacturers, importers and downstream users have included in the relevant chemical safety reports and safety data sheets, Derived No-Effect Levels (DNELs) relating to exposure of workers of 14,4 mg/m³ for exposure by inhalation and 4,8 mg/kg/day for dermal exposure.</p> <p>2. Shall not be manufactured, or used, as a substance on its own or in mixtures in a concentration equal to or greater than 0,3 % after 9 May 2020 unless manufacturers and downstream users take the appropriate risk management measures and provide the appropriate operational conditions to ensure that exposure of workers is below the DNELs specified in paragraph 1.</p> <p>3. By way of derogation from paragraphs 1 and 2, the obligations laid down therein shall apply from 9 May 2024 in relation to placing on the market for use, or use, as a solvent or reactant in the process of coating wires.</p>
<p>72. The substances listed in column 1 of the Table in Appendix 12</p>	<p>1. Shall not be placed on the market after 1 November 2020 in any of the following:</p> <p>(a) clothing or related accessories;</p> <p>(b) textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an</p>



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	<p>extent similar to clothing;</p> <p>(c) footwear;</p> <p>if the clothing, related accessory, textile other than clothing or footwear is for use by consumers and the substance is present in a concentration, measured in homogeneous material, equal to or greater than that specified for that substance in Appendix 12.</p> <p>2. By way of derogation, in relation to the placing on the market of formaldehyde [CAS No 50-00-0] in jackets, coats or upholstery, the relevant concentration for the purposes of paragraph 1 shall be 300 mg/kg during the period between 1 November 2020 and 1 November 2023. The concentration specified in Appendix 12 shall apply thereafter.</p> <p>3. Paragraph 1 shall not apply to:</p> <p>(a) clothing, related accessories or footwear, or parts of clothing, related accessories or footwear, made exclusively of natural leather, fur or hide;</p> <p>(b) non-textile fasteners and non-textile decorative attachments;</p> <p>(c) second-hand clothing, related accessories, textiles other than clothing or footwear</p> <p>(d) wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners.</p> <p>4. Paragraph 1 shall not apply to clothing, related accessories, textiles other than clothing, or footwear within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council (*) or Regulation (EU) 2017/745 of the European Parliament and of the Council (**).</p> <p>5. Paragraph 1(b) shall not apply to disposable textiles. 'Disposable textiles' means textiles that are designed to be used only once or for a limited time and are not intended for subsequent use for the same or a similar purpose.</p> <p>6. Paragraphs 1 and 2 shall apply without prejudice to the application of any stricter restrictions set out in this Annex or in other applicable Union legislation.</p> <p>7. The Commission shall review the exemption in paragraph 3(d) and, if appropriate, modify that point accordingly.</p> <p>(*) Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).</p> <p>(**) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).</p>
<p>73.</p> <p>(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol</p>	<p>1. Shall not be placed on the market for supply to the general public after 2 January 2021 individually or in any combination, in a concentration equal to or greater than 2 ppb by weight of the mixtures containing organic</p>



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<p>Any of its mono-, di- or tri-O-(alkyl) derivatives (TDFAs</p>	<p>solvents, in spray products.</p> <p>2. For the purpose of this entry, 'spray products' means aerosol dispensers, pump sprays, trigger sprays, marketed for proofing or impregnation spray applications.</p> <p>3. Without prejudice to the implementation of other Union provisions concerning the classification, packaging and labelling of substances and mixtures, the packaging of spray products containing (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and/or TDFAs combined with organic solvents as referred to in paragraph 1 and placed on the market for professional use shall be marked clearly and indelibly: 'for professional users only' and 'Fatal if inhaled' with the pictogram GHS06.</p> <p>4. Section 2.3 of Safety Data Sheets shall contain the following information: 'mixtures of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and/or any of its mono-, di- or tri-O-(alkyl) derivatives in a concentration equal to or greater than 2 ppb and organic solvents in spray products, are for professional users only and marked "Fatal if inhaled"'. </p> <p>5. Organic solvents referred to in paragraph 1, 3, and 4 include organic solvents used as aerosol propellants.</p>
<p>74. Diisocyanates, $O = C=N-R-N = C=O$, with R an aliphatic or aromatic hydrocarbon unit of unspecified length</p>	<p>1. Shall not be used as substances on their own, as a constituent in other substances or in mixtures for industrial and professional use(s) after 24 August 2023, unless:</p> <p>(a) the concentration of diisocyanates individually and in combination is less than 0,1 % by weight, or</p> <p>(b) the employer or self-employed ensures that industrial or professional user(s) have successfully completed training on the safe use of diisocyanates prior to the use of the substance(s) or mixture(s).</p> <p>2. Shall not be placed on the market as substances on their own, as a constituent in other substances or in mixtures for industrial and professional use(s) after 24 February 2022, unless:</p> <p>(a) the concentration of diisocyanates individually and in combination is less than 0,1 % by weight, or</p> <p>(b) the supplier ensures that the recipient of the substance(s) or mixture(s) is provided with information on the requirements referred to in point (b) of paragraph 1 and the following statement is placed on the packaging, in a manner that is visibly distinct from the rest of the label information: 'As from 24 August 2023 adequate training is required before industrial or professional use'.</p> <p>3. For the purpose of this entry 'industrial and professional user(s)' means any worker or self-employed worker handling diisocyanates on their own, as a constituent in other substances or in mixtures for industrial</p>



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and professional use(s) or supervising these tasks.

4. The training referred to in point (b) of paragraph 1 shall include the instructions for the control of dermal and inhalation exposure to diisocyanates at the workplace without prejudice to any national occupational exposure limit value or other appropriate risk management measures at national level. Such training shall be conducted by an expert on occupational safety and health with competence acquired by relevant vocational training. That training shall cover as a minimum:

(a) the training elements in point (a) of paragraph 5 for all industrial and professional use(s).

(b) the training elements in points (a) and (b) of paragraph 5 for the following uses:

- handling open mixtures at ambient temperature (including foam tunnels);
- spraying in a ventilated booth;
- application by roller;
- application by brush;
- application by dipping and pouring;
- mechanical post treatment (e.g. cutting) of not fully cured articles which are not warm anymore;
- cleaning and waste;
- any other uses with similar exposure through the dermal and/or inhalation route;

(c) the training elements in points (a), (b) and (c) of paragraph 5 for the following uses:

- handling incompletely cured articles (e.g. freshly cured, still warm);
- foundry applications;
- maintenance and repair that needs access to equipment;
- open handling of warm or hot formulations ($> 45\text{ }^{\circ}\text{C}$);
- spraying in open air, with limited or only natural ventilation (includes large industry working halls) and spraying with high energy (e.g. foams, elastomers);
- and any other uses with similar exposure through the dermal and/or inhalation route.

5. Training elements:

(a) general training, including on-line training, on:

- chemistry of diisocyanates;
- toxicity hazards (including acute toxicity);
- exposure to diisocyanates;
- occupational exposure limit values;



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- how sensitisation can develop;
- odour as indication of hazard;
- importance of volatility for risk;
- viscosity, temperature, and molecular weight of diisocyanates;
- personal hygiene;
- personal protective equipment needed, including practical instructions for its correct use and its limitations;
- risk of dermal contact and inhalation exposure;
- risk in relation to application process used;
- skin and inhalation protection scheme;
- ventilation;
- cleaning, leakages, maintenance;
- discarding empty packaging;
- protection of bystanders;
- identification of critical handling stages;
- specific national code systems (if applicable);
- behaviour-based safety;
- certification or documented proof that training has been successfully completed

(b) intermediate level training, including on-line training, on:

- additional behaviour-based aspects;
- maintenance;
- management of change;
- evaluation of existing safety instructions;
- risk in relation to application process used;
- certification or documented proof that training has been successfully completed

(c) advanced training, including on-line training, on:

- any additional certification needed for the specific uses covered;
- spraying outside a spraying booth;
- open handling of hot or warm formulations ($> 45^{\circ}\text{C}$);
- certification or documented proof that training has been successfully completed

6. The training shall comply with the provisions set by the Member State in which the industrial or professional user(s) operate. Member States may implement or continue to apply their own national requirements for the use of the substance(s) or mixture(s), as long as the minimum requirements set out in paragraphs 4 and 5 are met.

7. The supplier referred to in point (b) of paragraph 2 shall ensure that the recipient is provided with training material and courses pursuant to paragraphs 4 and 5 in the official language(s) of the Member State(s)



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	<p>where the substance(s) or mixture(s) are supplied. The training shall take into consideration the specificity of the products supplied, including composition, packaging, and design.</p> <p>8. The employer or self-employed shall document the successful completion of the training referred to in paragraphs 4 and 5. The training shall be renewed at least every five years.</p> <p>9. Member States shall include in their reports pursuant to Article 117(1) the following information:</p> <p>(a) any established training requirements and other risk management measures related to the industrial and professional uses of diisocyanates foreseen in national law;</p> <p>(b) the number of cases of reported and recognised occupational asthma and occupational respiratory and dermal diseases in relation to diisocyanates;</p> <p>(c) national exposure limits for diisocyanates, if there are any;</p> <p>(d) information about enforcement activities related to this restriction.</p> <p>10. This restriction shall apply without prejudice to other Union legislation on the protection of safety and health of workers at the workplace.</p>
<p>75.</p> <p>Substances falling within one or more of the following points:</p> <p>(a) substances classified as any of the following in Part 3 of Annex VI to Regulation (EC) No 1272/2008:</p> <ul style="list-style-type: none"> — carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, but excluding any such substances classified due to effects only following exposure by inhalation — reproductive toxicant category 1A, 1B or 2 but excluding any such substances classified due to effects only following exposure by inhalation — skin sensitiser category 1, 1A or 1B — skin corrosive category 1, 	<p>1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:</p> <p>(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;</p> <p>(b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;</p> <p>(c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;</p> <p>(d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye</p>



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<p>1A, 1B or 1C or skin irritant category 2</p> <p>— serious eye damage category 1 or eye irritant category 2</p> <p>(b) substances listed in Annex II to Regulation (EC) No 1223/2009 of the European Parliament and of the Council</p> <p>(c) substances listed in Annex IV to Regulation (EC) No 1223/2009 for which a condition is specified in at least one of the columns g, h and i of the table in that Annex</p> <p>(d) substances listed in Appendix 13 to this Annex.</p> <p>The ancillary requirements in paragraphs 7 and 8 of column 2 of this entry apply to all mixtures for use for tattooing purposes, whether or not they contain a substance falling within points (a) to (d) of this column of this entry.</p>	<p>irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:</p> <p>(i) 0,1 % by weight, if the substance is used solely as a pH regulator;</p> <p>(ii) 0,01 % by weight, in all other cases;</p> <p>(e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;</p> <p>(f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:</p> <p>(i) 'Rinse-off products';</p> <p>(ii) 'Not to be used in products applied on mucous membranes';</p> <p>(iii) 'Not to be used in eye products';</p> <p>(g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column;</p> <p>(h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.</p> <p>2. For the purposes of this entry use of a mixture 'for tattooing purposes' means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.</p> <p>3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.</p> <p>4. By way of derogation, paragraph 1 shall not apply to the following</p>
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substances until 4 January 2023:

- (a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
- (b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).

5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.

6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.

7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:

- (a) the statement 'Mixture for use in tattoos or permanent make-up';
- (b) a reference number to uniquely identify the batch;
- (c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. 'Ingredient' means any substance added during the process of formulation and present in the mixture for use for tattooing



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purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;

(d) the additional statement 'pH regulator' for substances falling under point (d)(i) of paragraph 1;

(e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;

(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13;

(g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.

The information shall be clearly visible, easily legible and marked in a way that is indelible.

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.

Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph.

8. Mixtures that do not contain the statement 'Mixture for use in tattoos or permanent make-up' shall not be used for tattooing purposes.

9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).



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10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

Remark: Appendix 12 as below:

Appendix 12

Entry 72 — restricted substances and maximum concentration limits by weight in homogeneous materials:

Substances	Index- No	CAS No	EC No	Concentration limit by weight
Cadmium and its compounds (listed in Annex XVII, Entry 28, 29, 30, Appendices 1-6)	—	—	—	1 mg/kg after extraction (expressed as Cd metal that can be extracted from the material)
Chromium VI compounds (listed in Annex XVII, Entry 28, 29, 30, Appendices 1-6)	—	—	—	1 mg/kg after extraction (expressed as Cr VI that can be extracted from the material)
Arsenic compounds (listed in Annex XVII, Entry 28, 29, 30, Appendices 1-6)	—	—	—	1 mg/kg after extraction (expressed as As metal that can be extracted from the material)
Lead and its compounds (listed in Annex XVII, Entry 28, 29, 30, Appendices 1-6)	—	—	—	1 mg/kg after extraction (expressed as Pb metal that can be extracted from the material)
Benzene	601-020-00-8	71-43-2	200-753-7	5 mg/kg
Benz[a]anthracene	601-033-00-9	56-55-3	200-280-6	1 mg/kg
Benz[e]acephenanthrylene	601-034-00-4	205-99-2	205-911-9	1 mg/kg
benzo[a]pyrene; benzo[def]chrysene	601-032-00-3	50-32-8	200-028-5	1 mg/kg
Benzo[e]pyrene	601-049-00-6	192-97-2	205-892-7	1 mg/kg
Benzo[j]fluoranthene	601-035-00-X	205-82-3	205-910-3	1 mg/kg
Benzo[k]fluoranthene	601-036-00-5	207-08-9	205-916-6	1 mg/kg
Chrysene	601-048-00-0	218-01-9	205-923-4	1 mg/kg
Dibenz[a,h]anthracene	601-041-00-2	53-70-3	200-181-8	1 mg/kg
α, α,α,4-tetrachlorotoluene;	602-093-00-9	5216-25-1	226-009-1	1 mg/kg



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p-chlorobenzotrichloride				
α , α , α -trichlorotoluene; benzotrichloride	602-038-00-9	98-07-7	202-634-5	1 mg/kg
α -chlorotoluene; benzyl chloride	602-037-00-3	100-44-7	202-853-6	1 mg/kg
Formaldehyde	605-001-00-5	50-00-0	200-001-8	75 mg/kg
1,2-benzenedicarboxylic acid; di-C 6-8-branched alkylesters, C 7-rich	607-483-00-2	71888-89- 6	276-158-1	1 000 mg/kg (individually or in combination with other phthalates in this entry or in other entries of Annex XVII that are classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 in any of the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B
Bis(2-methoxyethyl) phthalate	607-228-00-5	117-82-8	204-212-6	1 000 mg/kg (individually or in combination with other phthalates in this entry or in other entries of Annex XVII that are classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 in any of the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B
Diisopentylphthalate	607-426-00-1	605-50-5	210-088-4	1 000 mg/kg (individually or in combination with other phthalates in this entry or in other entries of Annex XVII that are classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 in any of the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B
Di-n-pentyl phthalate (DPP)	607-426-00-1	131-18-0	205-017-9	1 000 mg/kg (individually or in combination with other phthalates in this entry or in other entries of Annex XVII that are classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 in any of the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B
Di-n-hexyl phthalate (DnHP)	607-702-00-1	84-75-3	201-559-5	1 000 mg/kg (individually or in combination with other phthalates in this entry or in other entries of Annex XVII that are classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 in any of the



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				hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B
N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone (NMP)	606-021-00-7	872-50-4	212-828-1	3 000 mg/kg
N,N-dimethylacetamide (DMAC)	616-011-00-4	127-19-5	204-826-4	3 000 mg/kg
N,N-dimethylformamide; dimethyl formamide (DMF)	616-001-00-X	68-12-2	200-679-5	3 000 mg/kg
1,4,5,8-tetraaminoanthraquinone; C.I. Disperse Blue 1	611-032-00-5	2475-45-8	219-603-7	50 mg/kg
Benzenamine, 4,4'-(4-iminocyclohexa-2,5-dienylidenemethylene)dianiline hydrochloride; C.I. Basic Red 9	611-031-00-X	569-61-9	209-321-2	50 mg/kg
[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride; C.I. Basic Violet 3 with $\geq 0,1$ % of Michler's ketone (EC no. 202-027-5)	612-205-00-8	548-62-9	208-953-6	50 mg/kg
4-chloro-o-toluidinium chloride	612-196-00-0	3165-93-3	221-627-8	30 mg/kg
2-Naphthylammoniumacetate	612-071-00-0	553-00-4	209-030-0	30 mg/kg
4-methoxy-m-phenylene diammonium sulphate; 2,4-diaminoanisole sulphate	612-200-00-0	39156-41-7	254-323-9	30 mg/kg
2,4,5-trimethylaniline hydrochloride	612-197-00-6	21436-97-5	—	30 mg/kg
Quinoline	613-281-00-5	91-22-5	202-051-6	50 mg/kg

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