

L.N 346 of 2003

**PRODUCT SAFETY ACT, 2001
(ACT NO. V OF 2001)**

Dangerous Substances and Preparations (Restrictions) Regulations, 2003

IN exercise of the powers conferred by article 38 of the Product Safety Act, the Minister of Finance and Economic Affairs, on the advice of the Malta Standards Authority, has made the following regulations:

1. The title of these regulations is the Dangerous Substances and Preparations (Restrictions) Regulations, 2003. Citation.

2.1 These regulations shall apply to the marketing and use of the dangerous substances and preparations listed in the Schedules hereto. Applicability.

2.2 These regulations shall not apply to:-

(a) the carriage of dangerous substances and preparations by rail, road, inland waterway, sea or air;

(b) dangerous substances and preparations intended for export;

(c) substances and preparations in transit and subject to customs inspection, provided that they undergo no processing.

3.1 For the purposes of this Order, the following definitions shall apply, unless the context otherwise requires:- Definitions.

‘substances’ means chemical elements and their compounds as they occur in the natural state or as produced by industry;

‘preparations’ means mixtures or solutions composed of two or more substances.

4.1 The dangerous substances and preparations listed in the Schedules to these regulations may only be placed on the market or used subject to the conditions specified therein. Restrictions on marketing.

4.2 The provisions of sub-regulation 4.1 shall not apply to marketing or use for Research and Development or analysis purposes.

5.1 The Foodstuffs, Chemicals and Cosmetics Directorate of the Malta Standards Authority shall make available to the general public an updated copy of the Appendix to Council Directive 76/769/EEC containing substances classified as carcinogenic, mutagenic or toxic to reproduction of category 1 or 2 as referred to in points 29, 30 and 31 of the First Schedule to these regulations.

References to
Council
Directive
76/769/EEC.

6.1 The Dangerous Substances and Preparations (Restrictions) Regulations, 2002 are hereby repealed insofar as certain provisions thereof and of the Dangerous Substances and Preparations (Restrictions) Regulations, 2001 shall continue to apply as indicated in the First Schedule to these regulations.

Repeal of
L.N. 142 of
2002.

L.N. 152 of
2001.

FIRST SCHEDULE

Restrictions on Dangerous Substances and Preparations

	Designation of the substance, of the groups of substances or of the preparation	Conditions of restriction
1.	<ul style="list-style-type: none"> - Polychlorinated biphenyls (PCB) except mono- and dichlorinated biphenyls - Polychlorinated terphenyls (PCTs) - Preparations, including waste oils, with a PCB or PCT content higher than 0.005 % by weight 	May not be used.
2.	Chloro-1-ethylene (monomer vinyl chloride)	May not be used as aerosol propellant for any use whatsoever.
3.	<p>Liquid substances or preparations, which are regarded as dangerous according to the definitions in Article 2(2) and the criteria in Annex VI, Part II.D to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ⁽¹⁾, as adapted to technical progress by Commission Directives 93/21/EEC ⁽²⁾ and 96/54/EC ⁽³⁾</p>	<p>May not be used in:</p> <ul style="list-style-type: none"> - ornamental objects intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays. - tricks, jokes. - games for one or more participants, or any object intended to be used as such, even with ornamental aspects. <p>2. Without prejudice to the above, substances and preparations which:</p> <ul style="list-style-type: none"> - present an aspiration hazard and are labelled with R65, and - can be used as fuel in decorative lamps, and - are placed on the market in packaging of a capacity of 15 litres or less, <p>may not contain a colouring agent, unless required for fiscal reasons, or perfume or both.</p> <p>Without prejudice to the application of other provisions on the classification, packaging and labelling of dangerous substances and preparations, the packaging of substances and preparations covered by paragraph 2,</p>

¹ OJ No L 196, 16.8.1967, p.1

² OJ No L 110, 4.5.1993, p.20

³ OJ L 248, 30.9.1996, p.1

	Designation of the substance, of the groups of substances or of the preparation	Conditions of restriction
		where intended for use in lamps, must be marked legibly and indelibly as follows: “Keep lamps filled with this liquid out of the reach of children.”
4.	Tris (2,3 dibromopropyl) phosphate, CAS No (Chemical Abstract Service Number) 126-72-7	May not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin.
5.	Benzene CAS No. (Chemical Abstract Service Number) 71-43-2	Not permitted in toys or parts of toys as placed in the market where the concentration of benzene in the free state is in excess of 5 mg/kg of the weight of the toy or part of toy. May not be used in concentrations equal to, or greater than, 0.1 % by mass in substances or preparations placed on the market. However, this provision shall not apply to: (a) motor fuels which are covered by Directive 85/210/EEC; (b) substances and preparations for use in industrial processes not allowing for the emission of benzene in quantities in excess of those laid down in existing legislation; (c) waste covered by Directives 75/442/EEC ⁽⁴⁾ and 78/319/EEC ⁽⁵⁾
6.	Asbestos fibres	
6.1	Crocidolite, CAS No 12001-28-4 Amosite, CAS No 12172-73-5 Anthophyllite asbestos, CAS No 77536-67-5 Actinolite asbestos, CAS No 77536-66-4 Tremolite asbestos, CAS No 77536-68-6	6.1. The placing on the market and use of these fibres and of products containing these fibres added intentionally shall be prohibited.
6.2	Chrysotile, CAS No 12001-29-5	6.2. As from 1 st January 2005, the placing on the market and use of this fibre and of products containing this

⁴ OJ No L 194, 25.7.1975, p.39

⁵ OJ No L 84, 31.3.1978, p.43

	Designation of the substance, of the groups of substances or of the preparation	Conditions of restriction
		<p>fibre added intentionally shall be prohibited with the exception of diaphragms for existing electrolysis installations until they reach the end of their service life, or until suitable asbestos-free substitutes become available, whichever is the sooner.</p> <p>The use of products containing asbestos fibres referred to in points 6.1 and 6.2 which were already installed and/or in service before 1st January 2005 shall continue to be authorised until they are disposed of or reach the end of their service life.</p> <p>The provisions of points 6.1 and 6.2 of the First Schedule of the Dangerous Substances and Preparations (Restrictions) Regulations 2001 (L.N. 152 of 2001) shall continue to apply between 1st July 2002 and 1st January 2005.</p> <p>Without prejudice to the application of other provisions on the classification, packaging and labelling of dangerous substances and preparations, the placing on the market and use of these fibres and of products containing these fibres, as authorised according to the preceding derogations, may be permitted only if the products bear a label in accordance with the provisions of the Schedule of the Asbestos Products (Labelling) Regulations, 2001 (L.N. 60 of 2001).</p>
7.	<p>di-isononyl phthalate (DINP) CAS No.: 28553-12-0 Einecs No.: 249-079-5</p> <p>di(2-ethylhexyl) phthalate (DEHP) CAS No.: 117-81-7 Einecs No.: 204-211-0</p> <p>di-n-octyl phthalate (DNOP)</p>	<p>Not permitted in toys and childcare articles as placed on the market and intended to be placed in the mouth by children of less than three years of age, and made of, or in part made of, soft PVC, where the concentration of these substances is in excess of 0.1 % by weight.</p>

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	CAS No.: 117-84-0 Einecs No.: 204-214-7 di-iso-decyl phthalate (DIDP) CAS No.: 26761-40-0 Einecs No.: 247-977-1 butyl benzyl phthalate (BBP) CAS No.: 85-68-7 Einecs No.: 201-622-7 dibutyl phthalate (DBP) CAS No.: 84-74-2 Einecs No.: 201-557-4	For the purposes of this point, the following definitions shall apply: ‘toy’ shall mean any product designed or clearly intended for use in play by children, ‘childcare article’ shall mean any product intended to facilitate sleep, relaxation, the feeding of children, or sucking on the part of children.
8.	Tris-aziridinyl)-phosphin oxide CAS No 5455-55-1	May not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin.
9.	Polybromobiphenyls (PBB) CAS No 59536-65-1	May not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin.
10.	Soap bark powder (<i>Quillaja saponaria</i>) and its derivatives containing saponines Powder of the roots of <i>Helleborus viridis</i> and <i>Helleborus niger</i> Powder of the roots of <i>Veratrum album</i> and <i>Veratrum nigrum</i> Benzydine and/or its derivatives <i>o</i> -nitrobenzaldehyde CAS No 552-89-6 Wood powder	May not be used in jokes and hoaxes or in objects intended to be used as such, for instance as a constituent of sneezing powder and stink bombs
11.	Ammonium sulphide and ammonium hydrogen sulphide CAS No 12135-76-1 CAS No 12124-99-1 Ammonium polysulphide CAS No 12259-92-6	May not be used in jokes and hoaxes or in objects intended to be used as such, for instance as a constituent of sneezing powder and stink bombs
12.	Volatile esters of bromoacetic acids: Methyl bromoacetate	May not be used in jokes and hoaxes or in objects intended to be used as such, for instance as a constituent of sneezing

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	CAS No 96-32-2 Ethyl bromoacetate CAS No 105-36-2 Propyl bromoacetate Butyl bromoacetate	powder and stink bombs.
13.	2-naphthylamine CAS No 91-59-8 and its salts	<p>May not be used in concentrations equal to or greater than 0.1 % by weight in substances and preparations placed on the market.</p> <p>However, this provision shall not apply to waste containing one or more of these substances and covered by Directives 75/442/EEC and 78/319/EEC.</p> <p>Such substances and preparations may not be sold to the general public.</p> <p>Without prejudice to the application of other provisions on the classification, packaging and labelling of dangerous substances and preparations, the packaging of such preparations shall be legibly and indelibly marked as follows: “Restricted to professional users”.</p>
14.	Benzidine CAS No 92-87-5 and its salts	<p>May not be used in concentrations equal to or greater than 0.1 % by weight in substances and preparations placed on the market.</p> <p>However, this provision shall not apply to waste containing one or more of these substances and covered by Directives 75/442/EEC and 78/319/EEC.</p> <p>Such substances and preparations may not be sold to the general public.</p> <p>Without prejudice to the application of other provisions on the classification, packaging and labelling of dangerous substances and preparations, the packaging of such preparations shall be legibly and indelibly marked as follows:</p>

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		“Restricted to professional users”.
15.	4-nitrobiphenyl CAS No 92-93-3	<p>May not be used in concentrations equal to or greater than 0.1 % by weight in substances and preparations placed on the market.</p> <p>However, this provision shall not apply to waste containing one or more of these substances and covered by Directives 75/442/EEC and 78/319/EEC.</p> <p>Such substances and preparations may not be sold to the general public. Without prejudice to the application of other provisions on the classification, packaging and labelling of dangerous substances and preparations, the packaging of such preparations shall be legibly and indelibly marked as follows: “Restricted to professional users”.</p>
16.	4-aminobiphenyl CAS No 92-67-1 and its salts	<p>May not be used in concentrations equal to or greater than 0.1 % by weight in substances and preparations placed on the market.</p> <p>However, this provision shall not apply to waste containing one or more of these substances and covered by Directives 75/442/EEC and 78/319/EEC.</p> <p>Such substances and preparations may not be sold to the general public. Without prejudice to the application of other provisions on the classification, packaging and labelling of dangerous substances and preparations, the packaging of such preparations shall be legibly and indelibly marked as follows: “Restricted to professional users”.</p>
17.	Lead carbons: - neutral anhydrous carbonate	May not be used as substances and constituents of preparations intended for use as paints, except for the

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	PbCO ₃ , CAS No 598-63-0 - lead hydrocarbonate PbCO ₃ .Pb(OH) ₂ , CAS No 1319-46-6	restoration and maintenance of works of art and historic buildings and their interiors, authorized in accordance with the provision of ILO Convention 13 on the use of white lead in paint.
18.	Lead sulphates: PbSO ₄ (1:1) CAS No 7446-14-2 Pb _x SO ₄ CAS No 15739-80-7	May not be used as substances and constituents of preparations intended for use as paints, except for the restoration and maintenance of works of art and historic buildings and their interiors, authorized in accordance with the provision of ILO Convention 13 on the use of sulphates of lead in paint.
19.	Mercury compound	May not be used as substances and constituents of preparations intended for use: (a) to prevent the fouling by micro-organisms, plants or animals of: - 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; (b) in the preservation of wood; (c) in the impregnation of heavy-duty industrial textiles and yarn intended for their manufacture; (d) in the treatment of industrial waters, irrespective of their use.
20.	Arsenic compounds	1. May not be used as substances and constituents of preparations intended for use: (a) To prevent the fouling by micro-organisms, plants or animals of: — 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; (b) in the preservation of wood. Furthermore, wood so treated may not be placed on the market;

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		<p>(c) however, by way of derogation:</p> <p>(i) Relating to the substances and preparations in 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. Wood so treated may not be placed on the market before fixation of the preservative is completed.</p> <p>(ii) Relating to wood treated with CCA solutions in industrial installations according to point (i): this 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:</p> <ul style="list-style-type: none"> — 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 e.g. 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. <p>Without prejudice to the application of other provisions on the classification, packaging and labelling of dangerous substances and preparations, all treated wood placed on the market shall be individually labelled “For professional and industrial installation and use only,</p>

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		<p>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".</p> <p>(iii) Treated wood referred to under points (i) and (ii) may not be used:</p> <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 (ii), — in any application where the treated wood may come into contact with intermediate or finished products intended for human and/or animal consumption. <p>2. May not be used as substances and constituents of preparations intended for use in the treatment of industrial waters, irrespective of their use.</p>
21.	Organostannic compounds	<p>1. May not be placed on the market for use as substances and constituents of preparations when acting as biocides in free association paint.</p> <p>2. May not be placed on the market or used as substances and constituents of preparations which act as biocides to prevent the fouling by microorganisms, plants and animals of:</p> <ul style="list-style-type: none"> (a) tall craft irrespective of their length intended for use in marine, coastal, estuarine and inland waterways and lakes; (b) cages, floats, nets and

	Designation of the substance, of the groups of substances or of the preparation	Conditions of restriction
		<p>any other appliances or equipment used for fish or shellfish farming;</p> <p>(c) any totally or partly submerged appliance or equipment.</p> <p>3. May not be used as substances and constituents of preparations intended for use in the treatment of industrial waters.</p>
22.	<p>di-μ-oxo-di-n-butylstanniohydroxyborane (DBB) (C₈H₁₉BO₃Sn), CAS No 75113-37-0</p>	<p>Shall be prohibited in a concentration equal to or greater than 0.1 % in substances and constituents of preparations placed on the market. However, this provision shall not apply to this substance (DBB) or preparations containing it if these are intended solely for conversion into finished products, among which this substance will no longer feature in a concentration equal to or greater than 0.1 %.</p>
23.	<p>Pentachlorophenol (CAS No 87-86-5) and its salts and esters</p>	<p>Shall not be used in a concentration equal to or greater than 0,1 % by mass in substances or preparations placed on the market.</p> <p>By way of special exception, the competent authority may on a case-by-case basis, authorise specialised professionals to carry out <i>in situ</i> and for buildings of cultural, artistic and historical interest, or in emergencies, a remedial treatment of timber and masonry infected by dry rot fungus (<i>Serpula lacrymans</i>) and cubic rot fungi.</p> <p>In any case:</p> <p>(a) Pentachlorophenol used alone or as a component of preparations employed within the framework of the above exception must have a total hexachlorodibenzoparadioxin (HCDD) content of not more than two parts per million (ppm);</p> <p>(b) these substances and preparations</p>

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		<p>may not:</p> <ul style="list-style-type: none"> . be placed on the market except in packages of 20 litres or more; . be sold to the general public. <p>Without prejudice to the implementation of other provisions concerning the classification, packaging and labelling of dangerous substances and preparations, the packaging of such preparations should be marked clearly and indelibly:</p> <p>“Reserved for industrial and professional use”</p> <p>In addition, this provision shall not apply to waste covered by Directives 75/442/EEC ⁽⁶⁾ and 91/689/EEC ⁽⁷⁾.</p>
24.	Cadmium (CAS No 7440-43-9) and its compounds	<p>1.1 May not be used to give colour to finished products manufactured from the substances and preparations listed below:</p> <ul style="list-style-type: none"> - polyvinyl chloride (PVC) [3904 10] [3904 21] [3904 22] ⁽⁸⁾ - polyurethane (PUR) [3909 50] - low density polyethylene (ld PE), with the exception of low-density polyethylene used for the production of coloured masterbatch [3901 10] - cellulose acetate (CA) [3912 11] [3912 12] - cellulose acetate butyrate (CAB) [3912 11] [3912 12] - epoxy resins [3907 30] <p>In any case, whatever their use or intended final purpose, finished products or components of products manufactured from the substances and preparations listed above coloured with cadmium may not be placed on the market if their cadmium content (expressed as Cd metal) exceeds 0.01 % by mass of the plastic material.</p> <p>1.2 Section 1.1 also applies for:</p> <p>(a) finished products manufactured from the following substances and preparations:</p> <ul style="list-style-type: none"> - melamine-formaldehyde (MF) [3909 20] - urea-formaldehyde (UF) [3909 10] - unsaturated polyesters (UP) [3907 91] - polyethylene terephthalate (PET) [3907 60]

⁶ OJ L 194, 25.7.1975, p. 39.

⁷ OJ L 377, 31.12.1991, p. 20.

⁸ Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ No L 256, 7.9.1987).

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		<ul style="list-style-type: none"> - polybutylene terephthalate (PBT) - transparent/general-purpose polystyrene [3903 11] [3903 19] - acrylonitrile methylmethacrylate (AMMA) - cross-linked polyethylene (VPE) - high-impact polystyrene - polypropylene (PP) [3902 10] <p>(b) paints [3208] [3209]</p> <p>However, if the paints have a high zinc content, their residual concentration of cadmium must be as low as possible and at all events not exceed 0.1 % by mass.</p> <p>1.3 However, Sections 1.1 and 1.2 do not apply to products to be coloured for safety reasons.</p> <p>2.1 May not be used to stabilize the finished products listed below manufactured from polymers or copolymers of vinyl chloride:</p> <ul style="list-style-type: none"> - packaging materials (bags, containers, bottles, lids) [3923 29 10] [3920 41] [3920 42] - office or school supplies [3926 10] - fittings for furniture, coachwork or the like [3926 30] - articles of apparel and clothing accessories (including gloves) [3926 20] - floor and wall coverings [3918 10] - impregnated, coated, covered or laminated textile fabrics [5903 10] - imitation leather [4202] - gramophone records [8524 10] - tubes and pipes and their fittings [3917 23] - swing doors - vehicles for road transport (interior, exterior, underbody) - coating of steel sheet used in construction or in industry - insulation for electrical wiring <p>In any case, whatever their use or intended final purpose, the placing on the market of the above finished products or components of products manufactured from polymers or copolymers of vinyl chloride, stabilized by substances containing cadmium is prohibited, if their cadmium content (expressed as Cd metal) exceeds 0.01 % by mass of the polymer.</p> <p>2.2 However, Section 2.1 does not apply to finished products using cadmium-based stabilizers for safety reasons.</p> <p>3. Within the meaning of these Regulations, “cadmium plating” means any deposit or</p>

	Designation of the substance, of the groups of substances or of the preparation	Conditions of restriction
		<p>coating of metallic cadmium on a metallic surface.</p> <p>3.1 May not be used for cadmium plating metallic products or components of the products used in the sectors/applications listed below.</p> <p>(a) equipment and machinery for:</p> <ul style="list-style-type: none"> - 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] <p>(b) equipment and machinery for the production of:</p> <ul style="list-style-type: none"> - 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] <p>In any case, whatever their use or intended final purpose, the placing on the market of cadmium-plated products or components of such products used in the sectors/applications listed in (a) and (b) above and of products manufactured in the sectors listed in (b) above is prohibited.</p> <p>3.2 The provisions referred to in section 3.1 are also applicable to cadmium-plated products or components of such products when used in the sectors/applications listed in (a) and (b) below and to products manufactured in the sectors listed in (b) below:</p> <p>(a) equipment and machinery for the production of:</p> <ul style="list-style-type: none"> - paper and board [8419 32] [8439] [8441] - textiles and clothing [8444] [8445] [8447] [8448] [8449] [8451] [8452] <p>(b) equipment and machinery for the production of:</p> <ul style="list-style-type: none"> - 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]

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		<p>3.3 However, Sections 3.1 and 3.2 do not apply to:</p> <ul style="list-style-type: none"> - products and components of the products 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, on account of the reliability required of the apparatus on which they are installed.
25.	<p>Monomethyl-tetrachlorodiphenyl methane Trade name: Ugilec 141 CAS No 76253-60-6</p>	<p>The marketing and use of this substance and of preparations and products containing it shall be prohibited. By way of exception, this provision shall not apply:</p> <ol style="list-style-type: none"> 1) in the case of plant and machinery already in service on 18 June 1994 until such plant and machinery is disposed of; 2) in the case of the maintenance of plant and machinery already in service on 18 June 1994. <p>The placing on the second hand market of this substance, preparations containing this substance and plant/machinery containing this substance, is prohibited.</p>
26.	<p>Monomethyl-dichloro-diphenylmethane Trade name: Ugilec 121, Ugilec 21 CAS No – unknown</p>	<p>The marketing and use of this substance and of preparations and products containing it shall be prohibited.</p>
27.	<p>Monomethyl-dibromo-diphenylmethane Trade name: DBBT CAS No 99688-47-8</p>	<p>The marketing and use of this substance and of preparations and products containing it shall be prohibited.</p>
28.	<p>Nickel CAS No 7440-02-0 EINECS No 2311114 and its compounds</p>	<p>May not be used:</p> <ol style="list-style-type: none"> 1) in post assemblies which are inserted into pierced ears and other pierced parts of the human body during epithelization of the wound caused by piercing, whether subsequently removed or not, unless such post assemblies are homogenous and the concentration

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		<p>of nickel – expressed as mass of nickel to total mass – is less than 0.05 %;</p> <p>2) in products intended to come into direct and prolonged contact with the 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 products coming into direct and prolonged contact with the skin is greater than 0.5 µg/cm²/week;</p> <p>3) in products such as those listed in point 2 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 products 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 product.</p> <p>Furthermore, products which are the subject of points 1, 2 and 3 may not be placed on the market unless they conform to the requirements set out in those points.</p>
29.	<p>Substances which appear in Annex I to Directive 67/548/EEC classified as carcinogen category 1 or carcinogen category 2 and labelled at least as “Toxic (T)” with risk phrase R45: “May cause cancer” or risk phrase R49: “may cause cancer by inhalation”, and listed as follows:</p> <p>Carcinogen category 1</p>	<p>Without prejudice to the other points of this Schedule:</p> <p>May not be used in substances and preparations placed on the market for sale to the general public in individual concentration equal to or greater than:</p> <ul style="list-style-type: none"> - either the concentration specified in Annex I to Council Directive 67/548/EEC, or - the concentration specified in point

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	<p>See List 1 in the Appendix to Council Directive 76/769/EEC Carcinogen category 2 See List 2 in the Appendix to Council Directive 76/769/EEC</p>	<p>6, Table VI, of Annex I to Council Directive 88/379/EEC⁽⁹⁾, where no concentration limit appears in Annex I to Directive 67/548/EEC.</p> <p>Without prejudice to the implementation of other provisions relating to the classification, packaging and labelling of dangerous substances and preparations, the packaging of such substances and preparations must be marked legibly and indelibly as follows: “Restricted to professional users. Attention – Avoid exposure – obtain special instructions before use”. By way of derogation, this provision shall not apply to:</p> <ul style="list-style-type: none"> (a) medicinal or veterinary products as defined by Council Directive 65/65/EEC; (b) cosmetic products as defined by the Cosmetic Products Order, 2000; (c) motor fuels which are covered by Council Directive 85/210/EEC⁽¹⁰⁾, - mineral oil products intended for use as fuel in mobile or fixed combustion plants, - fuels sold in closed systems (e.g. liquid gas bottles); (d) artists’ paints covered by Council Directive 88/379/EEC.
30.	<p>Substances which appear in Annex I to Directive 67/548/EEC classified as mutagen category 1 or mutagen category 2 and labelled with risk phrase R46: “May cause heritable genetic damage”, and listed as follows:</p> <p>Mutagen category 1 See List 3 in the Appendix to Council</p>	<p>Without prejudice to the other points of this Schedule</p> <p>May not be used in substances and preparations placed on the market for sale to the general public in individual concentration equal to or greater than:</p> <ul style="list-style-type: none"> - either the concentration specified in Annex 1 to Directive 67/548/EEC,

⁹ OJ No L 187, 16.7.1988, p.14

¹⁰ OJ No L 96, 3.4.1985, p.25

	Designation of the substance, of the groups of substances or of the preparation	Conditions of restriction
	<p>Directive 76/769/EEC</p> <p>Mutagen category 2</p> <p>See List 4 in the Appendix to Council Directive 76/769/EEC</p>	<p>or</p> <ul style="list-style-type: none"> - the concentration specified in point 6, Table VI, of Annex I to Directive 88/379/EEC where no concentration limit appears in Annex 1 to Directive 67/548/EEC. <p>Without prejudice to the implementation of other provisions relating to the classification, packaging and labelling of dangerous substances and preparations, the packaging of such substances and preparations must be marked legibly and indelibly as follows: “Restricted to professional users. Attention – Avoid exposure – obtain special instructions before use”.</p> <p>This provision shall not apply to:</p> <ul style="list-style-type: none"> (a) medicinal or veterinary products as defined by Directive 65/65/EEC ⁽¹¹⁾; (b) cosmetic products as defined by the Cosmetic Products Order 2000 (L.N. 204 of 2000); (c) motor fuels which are covered by Directive 85/210/EEC ⁽¹²⁾, (d) mineral oil products intended for use as fuel in mobile or fixed combustion plants, (e) fuels sold in closed systems (e.g. liquid gas bottles), (f) artists’ paints covered by Directive 88/379/EEC ⁽¹³⁾
31.	<p>Substances which appear in Annex I to Directive 67/548/EEC classified as toxic for reproductive purposes category 1 or toxic for reproductive purposes category 2 and labelled with risk phrase R60: “May impair fertility” and/or R61: “May cause harm to the unborn child”, and listed as follows:</p>	<p>Without prejudice to the other points of this Schedule</p> <p>May not be used in substances and preparations placed on the market for sale to the general public in individual concentration equal to or greater than:</p> <ul style="list-style-type: none"> - either the concentration specified in Annex 1 to Directive 67/548/EEC, or

¹¹ OJ No L 22, 9.2.1965, p.369/65.

¹² OJ No L 96, 3.4.1985, p.25

¹³ OJ No L 187, 16.7.1988, p.14.

	Designation of the substance, of the groups of substances or of the preparation	Conditions of restriction
	<p>Toxic for reproductive purposes category 1 See List 5 in the Appendix to Council Directive 76/769/EEC</p> <p>Toxic for reproductive purposes category 2 See List 6 in the Appendix to Council Directive 76/769/EEC</p>	<p>- the concentration specified in point 6, Table VI, of Annex I to Directive 88/379/EEC where no concentration limit appears in Annex 1 to Directive 67/548/EEC.</p> <p>Without prejudice to the implementation of other provisions relating to the classification, packaging and labelling of dangerous substances and preparations, the packaging of such substances and preparations must be marked legibly and indelibly as follows: “Restricted to professional users. Attention – Avoid exposure – obtain special instructions before use”.</p> <p>This provision shall not apply to:</p> <ul style="list-style-type: none"> (a) medicinal or veterinary products as defined by Directive 65/65/EEC ⁽¹⁴⁾; (b) cosmetic products as defined by the Cosmetic Products Order 2000 (L.N. 204 of 2000); (c) motor fuels which are covered by Directive 85/210/EEC ⁽¹⁵⁾, (d) mineral oil products intended for use as fuel in mobile or fixed combustion plants, (e) fuels sold in closed systems (e.g. liquid gas bottles), (f) artists’ paints covered by Directive 88/379/EEC ⁽¹⁶⁾
32.	<p>Substances and preparations containing one or more of the following substances:</p> <ul style="list-style-type: none"> (a) Creosote, Einecs No 232-287-5, CAS No 8001-58-9 (b) Creosote oil, Einecs No 263-047-8, CAS No 61789-28-4 (c) Distillates (coal tar), naphthalene oils, Einecs No 283-484-8, CAS No 84650-04-4 	<p>As from 30th June 2003, the substances and preparations listed in point 32:</p> <ul style="list-style-type: none"> 1. May not be used in the treatment of wood. Furthermore, wood so treated may not be placed on the market 2. However by way of derogation: <ul style="list-style-type: none"> (i) Relating to the substances and preparations: these may be used for

¹⁴ OJ No 22, 9.2.1965, p.369/65.

¹⁵ OJ No L 96, 3.4.1985, p.25

¹⁶ OJ No L 187, 16.7.1988, p.14.

	Designation of the substance, of the groups of substances or of the preparation	Conditions of restriction
	<p>(d) Creosote oil, acenaphthalene fraction, Einecs No 292-605-3, CAS No 90640-84-9</p> <p>(e) Distillates (coal tar), upper, Einecs No. 266-026-1, CAS No 65996-91-0</p> <p>(f) Anthracene oil, Einecs No. 292-602-7, CAS No 90640-80-5</p> <p>(g) Tar Acids, Coal, Crude, Einecs No 266-019-3, CAS No 65996-85-2</p> <p>(h) Creosote, wood, Einecs No 232-419-1, CAS No 8021-39-4</p> <p>(i) Low temperature tar oil, alkaline, Einecs No 310-191-5, CAS No 122384-78-5</p>	<p>wood treatment in industrial installations or by professionals covered by legislation on the protection of workers for <i>in situ</i> retreatment only if they contain:</p> <p>(a) benzo-a-pyrene at a concentration of less than 0,005 % by mass</p> <p>(b) and water extractable phenols at a concentration of less than 3 % by mass.</p> <p>Such substances and preparations for use in wood treatment in industrial installations or by professionals:</p> <p>— may be placed on the market only in packaging of a capacity equal to or greater than 20 litres,</p> <p>— may not be sold to consumers.</p> <p>Without prejudice to the application of other provisions on the classification, packaging and labelling of dangerous substances and preparations, the packaging of such substances and preparations shall be legibly and indelibly marked “For use in industrial installations or professional treatment only”.</p> <p>(ii) Relating to wood treated in industrial installations or by professionals according to (i) which is placed on the market for the first time or retreated in-situ: this is permitted for professional and industrial use only, e.g. on railways, in electric power transmission and telecommunications, for fencing, for agricultural purposes (e.g. stakes for tree support) and in harbours and waterways.</p> <p>(iii) Relating to wood having been treated with substances listed in point 32(a) to (i) before 30th June 2003: the prohibition in point 1 on the placing on the market shall not apply where this is placed on the second-hand market for re-use.</p> <p>3. However, treated wood referred to</p>

	Designation of the substance, of the groups of substances or of the preparation	Conditions of restriction
		<p>under point 2(ii) and (iii) may not be 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 products mentioned above. <p>Provided further that the provisions of point 32 of the First Schedule of the Dangerous Substances and Preparations (Restrictions) Regulations 2001 (L.N. 152 of 2001) shall continue to apply between 1st July 2002 and 30th June 2003.</p>
<p>33.</p> <p>34.</p> <p>35.</p> <p>36.</p> <p>37.</p> <p>38.</p> <p>39.</p>	<p>Chloroform CAS No 67-66-3</p> <p>Carbon tetrachloride CAS No 56-23-5</p> <p>1,1,2-Trichloroethane CAS No 79-00-5</p> <p>1,1,2,2-Tetrachloroethane CAS No 79-34-5</p> <p>1,1,1,2-Tetrachloroethane CAS No 630-20-6</p> <p>Pentachloroethane CAS No 76-01-7</p> <p>1,1-Dichloroethylene CAS No 75-35-4</p>	<p>May not be used in concentrations equal to or greater than 0.1 % by weight in substances and preparations placed on the market for sale to the general public and/or in diffusive applications such as in surface cleaning and cleaning of fabrics.</p> <p>Without prejudice to the implementation of other provisions relating to the classification, packaging and labelling of dangerous substances and preparations, the packaging of such substances and preparations containing</p>

	Designation of the substance, of the groups of substances or of the preparation	Conditions of restriction
40.	1,1,1-Trichloroethane CAS No 71-55-6	<p>them in concentrations equal to or greater than 0.1 % shall be marked legibly and indelibly as follows: “For use in industrial installations only”.</p> <p>This provision shall not apply to:</p> <p>(a) medicinal or veterinary products as defined by Directive 65/65/EEC ⁽¹⁷⁾;</p> <p>(b) cosmetic products as defined by the Cosmetic Products Order 2000 (L.N. 204 of 2000);</p>
41.	<p>Substances either</p> <ul style="list-style-type: none"> - appearing in Annex I to Directive 67/548/EEC which are classified as flammable or extremely flammable and labelled as such, <p>or</p> <ul style="list-style-type: none"> - not yet appearing in Annex I to Directive 67/548/EEC but conforming to the criteria of flammability of Annex VI to Directive 67/548/EEC and being provisionally classified and labelled as flammable, highly flammable or extremely flammable according to Article 5(2) of Directive 67/548/EEC. 	<ol style="list-style-type: none"> 1. May not be used as such or in the form of preparations in aerosol generators marketed and intended for sale to the general public for entertainment and decorative purposes such as the following: <ul style="list-style-type: none"> - metallic glitter intended mainly for decorations, - artificial snow and frost, - ‘whoopie’ cushions, - silly string aerosols, - imitation excrement, - horn for parties, - decorative flakes and foams, - artificial cobwebs, - stink bombs, - etc. 2. Without prejudice to the implementation of other provisions relating to the classification, packaging and labelling of dangerous substances, the following words must appear legibly and indelibly on the packaging of aerosol generators referred to above: “For professional users only”. 3. Paragraphs 1 and 2 shall not apply to the aerosol generators referred to in Article 9a of Directive

¹⁷ OJ No 22, 9.2.1965, p.369/65.

	Designation of the substance, of the groups of substances or of the preparation	Conditions of restriction
		<p>75/324/EEC.</p> <p>4. The products referred to above may not be placed on the market unless they conform to the requirements indicated.</p>
42.	xx Hexachloroethane CAS No 67-72-1 EINECS No 2006664	May not be used in the manufacturing or processing of non-ferrous metals.
43.	Alkanes, C ₁₀ -C ₁₃ , chloro (short-chain chlorinated paraffins)	May not be placed on the market for use as substances or as constituents of other substances or preparations in concentrations higher than 1 %: <ul style="list-style-type: none"> — in metalworking; — for fat liquoring of leather.
44.	Azocolourants	As from 30 June 2004: <ol style="list-style-type: none"> 1. Azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in the Second Schedule, in detectable concentrations, i.e. above 30 ppm in the finished articles or in the dyed parts thereof, according to the testing method established in accordance with Article 2(a) of Council Directive 76/769/EEC, may 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: <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, chaircovers, 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. 2. Furthermore, the textile and leather Articles referred to in point 1 above may not be placed on the market unless

	Designation of the substance, of the groups of substances or of the preparation	Conditions of restriction
		<p>they conform to the requirements set out in that point;</p> <p>provided that, until 1 January 2005, this provision shall not apply to textile articles made of recycled fibres if the amines are released by residues deriving from previous dyeing of the same fibres and if the listed amines are released in concentrations below 70 ppm.</p> <p>3. Azodyes, which are contained in the "List of azodyes" that is hereby added to the Second Schedule, may not be placed on the market or used for colouring textile and leather articles as a substance or constituent of preparations in concentrations higher than 0,1 % by mass.</p> <p>provided that the provisions of point 44 of the Dangerous Substances and Preparations (Restrictions) Regulations 2002 (L.N. 142/2002), as amended by L.N. 394/2002, shall continue to apply until 30 June 2004.</p>
45.	Diphenyl ether, pentabromo derivative $C_{12}H_5Br_5O$	<p>As from 15 August 2004:</p> <p>1. May not be placed on the market or used as a substance or as a constituent of substances or of preparations in concentrations higher than 0.1 % by mass.</p> <p>2. Articles may not be placed on the market if they, or flame-retarded parts thereof, contain this substance in concentrations higher than 0.1 % by mass.</p>
46.	Diphenyl ether, octabromo derivative $C_{12}H_2Br_8O$	<p>As from 15 August 2004:</p> <p>1. May not be placed on the market or used as a substance or as a constituent of substances or of preparations in concentrations higher than 0.1 % by mass.</p>

	Designation of the substance, of the groups of substances or of the preparation	Conditions of restriction
		2. Articles may not be placed on the market if they, or flame-retarded parts thereof, contain this substance in concentrations higher than 0.1 % by mass.
47.	<p>(1) Nonylphenol $C_6H_4(OH)C_9H_{19}$</p> <p>(2) Nonylphenol ethoxylate $(C_2H_4O)_n C_{15}H_{24}O$</p>	<p>As from 17 January 2005:</p> <p>May not be placed on the market or used as a substance or constituent of preparations in concentrations equal or higher than 0,1 % by mass 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 pretreated 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:</p> <ul style="list-style-type: none"> — uses in controlled closed systems where the washing liquid is recycled or incinerated; <p>(6) manufacturing of pulp and paper;</p> <p>(7) cosmetic products;</p> <p>(8) other personal care products except:</p> <ul style="list-style-type: none"> — spermicides;

	Designation of the substance, of the groups of substances or of the preparation	Conditions of restriction
		(9) co-formulants in pesticides and biocides.
48.	Cement	<p>As from 17 January 2005:</p> <p>(1) Cement and cement-containing preparations may not be used or placed on the market, if they contain, when hydrated, more than 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 provisions on the classification, packaging and labelling of dangerous substances and preparations, the packaging of cement or cement-containing preparations shall be 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 preparations are handled solely by machines and in which there is no possibility of contact with the skin.</p>

Second Schedule

List of aromatic amines

	CAS number	Index number	EC number	Substances
1	92-67-1	612-072-00-6	202-177-1	biphenyl-4-ylamine 4-aminobiphenyl xenylamine
2	92-87-5	612-042-00-2	202-199-1	Benzidine
3	95-69-2		202-441-6	4-chloro-o-toluidine
4	91-59-8	612-022-00-3	202-080-4	2-naphthylamine
5	97-56-3	611-006-00-3	202-591-2	o-aminoazotoluene 4-amino-2',3- dimethylazobenzene 4-o-tolylazo-o-toluidine
6	99-55-8		202-765-8	5-nitro-o-toluidine
7	106-47-8	612-137-00-9	203-401-0	4-chloroaniline
8	615-05-4		210-406-1	4-methoxy-m- phenylenediamine
9	101-77-9	612-051-00-1	202-974-4	4,4'-methylenedianiline 4,4'- diaminodiphenylmethane
10	91-94-1	612-068-00-4	202-109-0	3,3'-dichlorobenzidine 3,3'-dichlorobiphenyl- 4,4'-ylenediamine
11	119-90-4	612-036-00-X	204-355-4	3,3'-dimethoxybenzidine o-dianisidine
12	119-93-7	612-041-00-7	204-358-0	3,3'-dimethylbenzidine 4,4'-bi-o-toluidine
13	838-88-0	612-085-00-7	212-658-8	4,4'-methylenedi-o- toluidine
14	120-71-8		204-419-1	6-methoxy-m-toluidine p- cresidine
15	101-14-4	612-078-00-9	202-918-9	4,4'-methylene-bis-(2- chloro-aniline) 2,2'-dichloro-4,4'- methylene-dianiline
16	101-80-4		202-977-0	4,4'-oxydianiline
17	139-65-1		205-370-9	4,4'-thiodianiline
18	95-53-4	612-091-00-X	202-429-0	o-toluidine 2-aminotoluene
19	95-80-7	612-099-00-3	202-453-1	4-methyl-m- phenylenediamine
20	137-17-7		205-282-0	2,4,5-trimethylaniline
21	90-04-0	612-035-00-4	201-963-1	o-anisidine 2- methoxyaniline
22	60-09-3	611-008-00-4	200-453-6	4-amino azobenzene

List of azodyes

	CAS Number	Index number	EC number	Substances
1	Not allocated Component 1: CAS-No: 118685-33-9 $C_{39}H_{30}ClCrN_7O_{12}S_2.2Na$ Component 2: $C_{46}H_{30}CrN_{10}O_{20}S_2.3Na$	611-070-00-2	405-665-4	A mixture of: disodium (6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)(1-(5-chloro-2-oxidophenylazo)-2-naphtholato)chromate(1-); trisodium bis(6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)chromate(1-)