

REACH Application for Juvenile Products in the EU

BACKGROUND

The REACH Regulation (Registration, Evaluation, Authorization and Restriction of Chemicals) applies to substances that are on their own, in mixtures or in articles. Special attention should be given to the Candidate List of substances of very high concern (SVHC) for authorization and restricted substances falling under Annex XVII as these two lists of substances are subject to different requirements.

LATEST UPDATE: SEPTEMBER 2024





OBLIGATIONS FOR RESTRICTED SUBSTANCES UNDER ANNEX XVII

Article 68 - Annex XVII will be amended by adopting new restrictions or amending current restrictions to address unacceptable risks to human health or the environment arising from the manufacture, use or placing on the market of substances on their own, in mixtures or in articles. Unless restrictions are met, regulated products should not use/contain the restricted substances under Annex XVII. Please be informed that the listed requirements in this document are for products covered by Regulation (EC) No. 1907/2006 on REACH. They do not cover additional EU member state legislation.

ENTRY NO.	SUBSTANCE	REQUIREMENT	MAIN MATERIALS / PRODUCTS CONCERNED	POSSIBLE APPLICATION - JUVENILE PRODUCTS	RELEVANCY ¹
1	Polychlorinated terphenyls (PCTs)	≤ 50 mg/kg	Mixtures	N/A	N/A
2	Chloroethene (vinyl chloride)	Prohibited	Propellant in aerosols	N/A	N/A
3	Dangerous liquid substances or mixtures with specified hazards under Regulation (EC) 1272/2008	Prohibited	 Tricks and jokes Mixtures and ornament articles intended to produce light/color effects by means of different phases 	N/A	N/A
4	Tris (2,3 dibromopropyl) phosphate (TDBPP)	Prohibited	Textile articles intended to come into contact with skin	Flame retardant	11
5	Benzene	 ≤ 5 mg/kg (toys or parts of toy) ≤ 0.1 % (constituent of substances or in mixtures) 	Toys and mixtures	N/A	N/A
6	Asbestos fibres: Crocidolite, amosite, anthophyllite, actinolite, tremolite and chrysotile	Prohibited	Articles and mixtures	N/A	N/A
7	Tris (aziridinyl) phosphinoxide (TEPA)	Prohibited	Textile articles intended to come into contact with skin	Flame retardant	11
8	Polybromobiphenyls; Polybrominatedbiphenyls (PBB)	Prohibited	Textile articles intended to come into contact with skin	Flame retardant	*
9	 a. Soap bark powder (Quillaja saponaria) and its derivatives containing saponines b. Powder of the roots of Helleborus viridis and Helleborus niger c. Powder of the roots of Veratrum album and Veratrum nigrum d. Benzidine and/or its derivatives e. o-Nitrobenzaldehyde f. Wood powder 	Prohibited	Mixtures and articles for jokes and hoaxes	N/A	N/A



ENTRY NO.	SUBSTANCE	REQUIREMENT	MAIN MATERIALS / PRODUCTS CONCERNED	POSSIBLE APPLICATION - JUVENILE PRODUCTS	RELEVANCY 1
10	a. Ammonium sulphide b. Ammonium hydrogen sulphide c. Ammonium polysulphide	Prohibited	Mixtures and articles for jokes and hoaxes	N/A	N/A
11	Volatile esters of bromoacetic acids: a. Methyl bromoacetate b. Ethyl bromoacetate c. Propyl bromoacetate d. Butyl bromoacetate	Prohibited	Mixtures and articles for jokes and hoaxes	N/A	N/A
12	2-Naphthylamine and its salts	≤ 0.1%	Mixtures	Dyes	
13	Benzidine and its salts	≤ 0.1%	Mixtures	Dyes	11
14	4-Nitrobiphenyl	≤ 0.1%	Mixtures	Dyes	11
15	4-Aminobiphenyl xenylamine and its salts	≤ 0.1%	Mixtures	Dyes	11
16	Lead carbonates: a. Neutral anhydrous carbonate (PbCO ₃) b. Trilead-bis(carbonate)- dihydroxide 2Pb CO ₃ - Pb(OH) ₂	Prohibited	Substances or mixtures intended for use as paints	Concerns paints	*
17	Lead sulphates: a. PbSO ₄ b. Pb _x SO ₄	Prohibited	Substances or mixtures intended for use as paints	Concerns paints	*
18	Mercury compounds	Prohibited	 a. to prevent fouling by micro-organisms, plants or animals in hulls of boats, cages, floats, nets and other appliances or equipment used for fish or shellfish farming b. in preservation of wood c. in impregnation of heavy-duty industrial textiles and yarn d. in the treatment of industrial waters 	Wood preservation treatment	*
18a	Mercury	Prohibited	Thermometers and other measuring devices for the general public	Mercury in thermometers – bath thermometers	1



ENTRY NO.	SUBSTANCE	REQUIREMENT	MAIN MATERIALS / PRODUCTS Concerned	POSSIBLE APPLICATION - JUVENILE PRODUCTS	RELEVANCY ¹
19	Arsenic compounds	Prohibited	a. to prevent fouling by micro-organisms, plants or animals in hulls of boats, cages, floats, nets and other appliances or equipment used for fish or shellfish farming b. in preservation of wood c. in the treatment of industrial waters	Wood protection treatments	1
20	Organostannic compounds	Prohibited as substances & in mixtures when acting as biocide in free association paint ≤ 0.1% Tri- substituted organostannic compounds (articles) ≤ 0.1% Dibutyltin (DBT) in mixtures and articles for the general public ≤ 0.1% Dioctyltin (DOT) in textile articles intended to come into contact with skin, gloves, footwear, wall and floor coverings, childcare articles, female hygiene products, nappies and RTV-2 moulding kits	Articles Paintings, inks, plastic pellets, textiles, gloves, footwear, wall and floor coverings, childcare articles, female hygiene products, nappies and RTV-2 moulding kits	Biocide PVC stabilizer in plastics Wood preservation	II I for tri- substituted, DBT and DOT
21	Di-µ-oxo-di-n- butylstanniohydroxyboran e / Dibutyltin hydrogen borate (DBB)	≤ 0.1%	Mixtures	Mixtures (paints or inks)	11



ENTRY NO.	SUBSTANCE	REQUIREMENT	MAIN MATERIALS / PRODUCTS CONCERNED	POSSIBLE APPLICATION - JUVENILE PRODUCTS	RELEVANCY ¹
23	Cadmium and its compounds	 ≤ 0.1% (mixtures and articles produced from synthetic organic polymers (plastics) ≤ 0.01% (paints with codes [3208] [3209]) ≤ 0.1% (paints with codes [3208] [3209] containing more than 10% zinc content) ≤ 0.1 (paint on painted articles) ≤ 0.01% (metal parts for making or in jewelry, imitation jewelry and hair accessories) 	Mixtures and articles	Plastic components, paints and paint on painted article Metal components for making or in jewelry and hair accessories	
24	Monomethyl - tetrachlorodiphenyl methane (Trade name: Ugilec 141)	Prohibited	Mixtures and articles	N/A	N/A
25	Monomethyl-dichloro- diphenyl methane (Trade name: Ugilec 121; Ugilec 21)	Prohibited	Mixtures and articles	N/A	N/A
26	Monomethyl-dibromo- diphenyl methane bromobenzylbromo- toluene, mixture of isomers (Trade name: DBBT)	Prohibited	Mixtures and articles	N/A	N/A
27	Nickel and its compounds	< 0.2 µg/cm²/week (post assemblies which are inserted into pierced ears and other pierced parts of the human body) ≤ 0.5 µg/cm²/week (direct and prolonged contact with the skin)	Skin contact metal surfaces	Metal parts in contact with the skin	1



ENTRY NO.	SUBSTANCE	REQUIREMENT	MAIN MATERIALS / PRODUCTS CONCERNED	POSSIBLE APPLICATION - JUVENILE PRODUCTS	RELEVANCY 1
28	Substances under Part 3 to Annex VI of Regulation (EC) 1272/2008 and classified as carcinogenic category 1A or 1B	Prohibited (substances, constituent of substances or in mixtures)	Substances and mixtures for the general public	N/A	N/A
29	Substances under Part 3 to Annex VI of Regulation (EC) 1272/2008 and classified as mutagenic category 1A or 1B	Prohibited (substances, constituent of substances or in mixtures)	Substances and mixtures for the general public	N/A	N/A
30	Substances under Part 3 to Annex VI of Regulation (EC) 1272/2008 and classified as reprotoxic category 1A or 1B	Prohibited (substances, constituent of substances or in mixtures)	Substances and mixtures for the general public	N/A	N/A
31	a. Creosote; wash oil	Prohibited (substances or	Substances or mixtures to treat	N/A	N/A
	b. Creosote oil; wash oil c. Distillates (coal tar), naphthalene oils; naphthalene oil	mixtures for treatment of wood, and treated wood)	wood, and treated wood		
	d. Creosote oil, acenaphthene fraction; wash oil				
	e. Distillates (coal tar), upper; heavy anthracene oil				
	f. Anthracene oil				
	g. Tar acids, coal, crude; crude phenols				
	h. Creosote, wood				
	i. Low temperature tar oil, alkaline; extract residues (coal), low temp. coal tar alkaline				
32	Chloroform	≤ 0.1% (constituent of other substances or in mixtures)	Mixtures	N/A	N/A
34	1,1,2-Trichloroethane	≤ 0.1% (constituent of other substances or in mixtures)	Mixtures	N/A	N/A
35	1,1,2,2-Tetrachloroethane	≤ 0.1% (constituent of other substances or in mixtures)	Mixtures	N/A	N/A



ENTRY NO.	SUBSTANCE	REQUIREMENT	MAIN MATERIALS / PRODUCTS Concerned	POSSIBLE APPLICATION - JUVENILE PRODUCTS	RELEVANCY 1
36	1,1,1,2-Tetrachloroethane	≤ 0.1% (constituent of other substances or in mixtures)	Mixtures	N/A	N/A
37	Pentachloroethane	≤ 0.1% (constituent of other substances or in mixtures)	Mixtures	N/A	N/A
38	1,1-Dichloroethene	≤ 0.1% (constituent of other substances or in mixtures)	Mixtures	N/A	N/A
40	Substances classified as flammable gases 1 or 2, flammable liquids 1, 2 or 3, flammable solids 1 or 2, Substances and mixtures, when contact with water, emit: Flammable gases 1, 2 or 3; pyrophoric liquids 1 or pyrophoric solids 1	Prohibited	Substances or mixtures in aerosol dispensers to general public for entertainment and decorative purposes	N/A	N/A
41	Hexachloroethane	Prohibited	Substances or mixtures for manufacturing or processing of non- ferrous metals	N/A	N/A
43	Azodyes	≤ 30 mg/kg each aromatic amine	Textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity	Dyes for textile and leather materials	1
45	Diphenylether, octabromo derivative	≤ 0.1% (articles) ≤ 0.1% (constituent of other substances or in mixtures)	Plastics Textiles	Flame retardant	11
46	a. Nonylphenol b. Nonylphenol ethoxylates	≤ 0.1 % for the specified purposes	Substance or mixture in detergents, textile processing agents, metal working, manufacturing of pulp and paper	Cleaning agent	11
46a	Nonylphenol ethoxylates	≤ 0.01%	Textile articles reasonably be expected to be washed in water during normal lifecycle	Textile articles reasonably be expected to be washed	11



ENTRY NO.	SUBSTANCE	REQUIREMENT	MAIN MATERIALS / PRODUCTS CONCERNED	POSSIBLE APPLICATION - JUVENILE PRODUCTS	RELEVANCY 1
47	Chromium VI compounds	≤ 2 mg/kg soluble chromium (VI) of total dry weight of cement	Cement	N/A	N/A
		≤ 3 mg/kg	Articles containing leather parts coming into contact with the skin	Leather in contact with skin	
48	Toluene	≤ 0.1% (used as substance or in mixtures)	Substance or mixture used in adhesives or spray paints for the general public	N/A	N/A
49	Trichlorobenzene	≤ 0.1% (used as substance or in mixtures)	Solvent for paints, other industrial mixtures	N/A	N/A
50	Polycyclic-aromatic hydrocarbons (PAH): a. Benzo[a]pyrene (BaP) b. Benzo[e]pyrene (BeP) c. Benzo[a]anthracene (BaA) d. Chrysen(CHR) e. Benzo[b]fluoranthene (BbFA) f. Benzo[j]fluoranthene (BjFA)	≤ 1 mg/kg each PAH (articles) ≤ 0.5 mg/kg each PAH (toys and childcare articles)	Rubber or plastic components in articles that come into direct and prolonged or short- term repetitive contact with the human skin or oral cavity under normal or reasonably foreseeable conditions of use	Rubber or plastic components in articles Rubber or plastic coatings	
	(BJFA) g. Benzo[k]fluoranthene (BkFA) h. Dibenzo[a,h]anthracene (DBAhA)	≤ 20 mg/kg (sum of 8 PAHs) and marked with a unique identification number of the batch	Granules or mulches as infill material in synthetic turf pitches, or in loose form on playgrounds or in sport applications	Granules or mulches in synthetic turf pitches or I n	N/A
51	a. Bis (2-ethylhexyl) phthalate (DEHP) b. Dibutyl phthalate (DBP)	< 0.1% (DEHP, DBP, BBP and DIBP), individually and in combination	Plasticized materials in toys and childcare articles	Plastic softener and paint spreading agent	1
	c. Benzyl butyl phthalate (BBP) d. Diisobutyl phthalate (DIBP)		Plasticized materials in articles (other than toys and childcare articles)	Plastic softener and paint spreading agent	1



ENTRY NO.	SUBSTANCE	REQUIREMENT	MAIN MATERIALS / PRODUCTS CONCERNED	POSSIBLE APPLICATION - JUVENILE PRODUCTS	RELEVANCY ¹
52	a. Di-"isononyl" phthalate (DINP) b. Di-"isodecyl" phthalate (DIDP) c. Di-n-octyl phthalate (DNOP)	≤ 0.1% (sum of DINP, DIDP and DNOP)	Plasticized materials in toys and childcare articles which can be placed in the mouth	Plastic softener and paint spreading agent	1
54	2-(2-methoxyethoxy) ethanol (DEGME)	≤ 0.1%	Paints, paint strippers, cleaning agents, self- shining emulsions or floor sealants for the general public	N/A	N/A
55	2-(2-butoxyethoxy) ethanol (DEGME)	≤ 3%	Spray paints or spray cleaners in aerosol dispensers for the general public	N/A	N/A
56	Methylenediphenyl diisocyanate (MDI) including the following specific isomers:	≤ 0.1%	Mixtures for the general public	N/A	N/A
	a. 4,4'- Methylenediphenyl diisocyanate				
	b. 2,4'- Methylenediphenyl diisocyanate				
	c. 2,2'- Methylenediphenyl diisocyanate				
57	Cyclohexane	< 0.1% as a constituent of neoprene-based contact adhesives greater than 350g	Solvent	N/A	N/A
58	Ammonium nitrate (AN)	≤ 28% of nitrogen for use as a solid fertilizer	Fertilizer	N/A	N/A
59	Dichloromethane	≤ 0.1 % (paint strippers for the general public or professionals)	Solvent	N/A	N/A
60	Acrylamide	\leq 0.1% (mixtures)	Grouting applications	N/A	N/A
61	Dimethylfumarate (DMFu)	\leq 0.1 mg/kg (articles or parts thereof)	Biocide (used for textile, leather, desiccants, anti-fungal agent)	Yes	1



ENTRY NO.	SUBSTANCE	REQUIREMENT	MAIN MATERIALS / PRODUCTS CONCERNED	POSSIBLE APPLICATION - JUVENILE PRODUCTS	RELEVANCY 1
62	Phenylmercury compounds a. Phenylmercury acetate b. Phenylmercury propionate c. Phenylmercury 2- ethylhexanoate d. Phenylmercury octanoate e. Phenylmercury neodecanoate	≤ 0.01% mercury	Mixtures and articles	N/A	N/A
63	Lead and its compounds	< 0.05% (jewelry) < 0.05% or \leq 0.05 µg/ cm ² /h (equivalent to \leq 0.05 µg/g/h) (articles for the general public or accessible parts thereof which may be placed in the mouth by children during normal or reasonably foreseeable conditions of use)	Jewelry Juvenile products	Juvenile products including clothing, footwear and childcare articles	1
64	1,4-Dichlorobenzene	< 1%	Substance or mixture for use or used in air fresheners or deodorizers in toilets, homes, offices or other indoor public areas	N/A	N/A
65	Inorganic ammonium salts	< 3 ppm by volume (2.12) mg/m ³) using CEN/TS 16516 with modifications from 14 July, 2018	Cellulose insulation mixtures or cellulose insulation articles	N/A	N/A
66	Bisphenol A (BPA)	< 0.02%	Thermal paper	N/A	N/A
68	C9-C14 PFCAs, including their salts and any	Prohibited	Substances	N/A	N/A
	combinations thereof C_9-C_{14} PFCA-related substances, including their salts and any combinations thereof	As a constituent of another substance, in mixtures or in articles: < 25 ppb (sum of C ₉ - C ₁₄ PFCAs and their salts) and < 260 ppb (sum of C ₉ -C ₁₄ PFCA-related substances)	As a constituent of another substance, in mixtures or in articles	Products with water, grease or dirt repellency	11



ENTRY NO.	SUBSTANCE	REQUIREMENT	MAIN MATERIALS / PRODUCTS CONCERNED	POSSIBLE APPLICATION - JUVENILE PRODUCTS	RELEVANCY 1
69	Methanol	< 0.6%	Windscreen washing or defrosting fluids	N/A	N/A
70	 Octamethylcyclotetra- siloxane (D4) Decamethylcylopenta- siloxane (D5) Dodecamethylcylo- hexasiloxane (D6) 	< 0.1% each of D4, D5 and D6	 Cosmetics Medical devices In vitro diagnostic medical devices (IVD) 	N/A	N/A
71	1-Methyl-2-pyrrolidone (NMP)	< 0.3% as substance on its own or in mixtures	Solvent or reactant in the process of coating wires	N/A	N/A
72	33 CMR 1A/1B substances in <u>Appendix 12</u>	See Appendix 12	 Clothing or related accessories Textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extend similar to clothing. Footwear 	Textile, leather and plasticized materials	1
73	3,3,4,4,5,5,6,6,7,7,8,8,8- tridecafluorooctyl) silanetriol Any of its mono-, di- or tri- O-(alkyl) derivatives (TDFAs)	< 2 ppb	Spray products containing organic solvents	N/A	N/A
74	Diisocyanates	< 0.1% as constituent in other substances or in mixtures for industrial and professional use	Substances and mixtures for industrial and professional use	N/A	N/A
75	Substances classified as: 1. CMR 1A, 1B or 2 2. Skin sensitizer 1, 1A or 1B 3. Skin corrosive 1, 1A, 1B or 1C or skin irritant 2 4. Serious eye damage 1 or eye irritant 2	See <u>entry 75</u> to Annex XVII of REACH	Tattoos	N/A	N/A
76	N,N-dimethylformamide	< 0.3% as a substance on its own, constituent of other substances, or in mixtures	Solvents	N/A	N/A



ENTRY NO.	SUBSTANCE	REQUIREMENT	MAIN MATERIALS / PRODUCTS CONCERNED	POSSIBLE APPLICATION - JUVENILE PRODUCTS	RELEVANCY ¹
77	Formaldehyde and formaldehyde releasers	≤ 0.062 mg/m ³ (wood-based articles) ≤ 0.080 mg/m ³ (articles other than furniture and wood- based articles)	 Foams Formaldehyde-based resins Textile and leather products Wallpaper Wood-based panels and products 	Wood-based articles Articles containing foam, textile and leather materials	1
78	Synthetic polymer microparticles (microplastics)	Prohibited as substances < 0.01% in mixtures if present to confer a sought-after characteristic (certain derogations apply)	1.Arts and crafts 2.Toys 3.Textiles 4.Cosmetics 5.Detergents	Products containing synthetic fabrics or plastics	II

Table 1

NOTE:

¹ Relevancy: indicates the level of importance for Juvenile products:

I: Clear and directly applicable requirements and limits

II: Concerns substances that may be used in the manufacture of juvenile products, surveillance needed

II*: Substances that may be used in the manufacture of juvenile products, with more precise concerns and possible applications N/A: Not applicable

IMPORTANT:

The content in Table 1 is for information only. Please see the REACH Regulation for full details on scope, requirements and testing methodologies.

OBLIGATIONS FOR SVHCs ON CANDIDATE LIST*

1. ARTICLE 31: DUTY TO COMMUNICATE INFORMATION ON SUBSTANCES IN MIXTURES

Suppliers of a substance that appears on the Candidate List have to provide a safety data sheet (SDS) for the substance to their customers. Suppliers of a mixture not classified as dangerous according to Regulation (EC) 1272/2008 on the Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation) have to provide the recipients on request, with a safety data sheet (SDS) if the mixture contains at least one substance on the Candidate List, present in at least 0.1% for non-gaseous mixtures or 0.2% for gaseous mixtures.

2. ARTICLE 33: DUTY TO COMMUNICATE INFORMATION ON SUBSTANCES IN ARTICLES

Suppliers of an article containing any SVHC on the Candidate List with a concentration above 0.1% shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of the substance.

Equivalent information should be supplied to consumers (the general public) if it is requested. The supplier has the duty to provide this information within 45 days upon receipt of this request.

3. ARTICLE 7(2): NOTIFICATION ON ARTICLES

EU Importers and EU manufacturers of articles containing substances that appear on the Candidate List may need to submit a notification to ECHA if the substance is present in the article above a concentration of 0.1% weight by weight (w/w) and the total amount of the substance in the articles exceeds one tonne per year.

*Beginning January 5, 2021, suppliers of articles containing SVHCs on the Candidate List in a concentration of more than 0.1% are obliged to submit information on these articles to the Substances of Concern In articles as such or in complex objects (Products) (SCIP Database) – an obligation established under amended Directive 2008/98/EC (Waste Framework Directive, WFD).

REFERENCES:

- Restricted Substances in Annex XVII of REACH
- SVHCs on Candidate List for Authorization

CONTACT US

For help with any questions, email us at <u>consumer.products@sgs.com</u>



Trusted means Tested.

