COCIR / BOMcheck List of Restricted and Declarable Substances for Medical Devices

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries. www.BOMcheck.net is an industry collaboration sharing one web database system to manage supply chain compliance to substance regulations around the world. The list is managed by the COCIR EHS Committee and BOMcheck Substance List Working Group and is aligned with the IPC-1752A Standard for Materials Declaration Management and the IPC-1752B Standard for Materials Declaration Management (http://www.ipc.org/ContentPage.aspx?pageid=Materials-Declaration) and the IEC 62474 screening of REACH Candidate List Substances. BOMcheck was appointed as co-chair of the IPC 1752A Standard in December 2010. BOMcheck was appointed as the UK National Expert for the IEC 62474 standard in June 2012 and took on the role of EMEA regional coordinator in December 2012. The IEC 62474 database of restricted and declarable substances replaced the Joint Industry Guide (JIG) in January 2014.

An international team of industry experts in North America, Europe and Asia Pacific identifies new regulatory requirements around the world which are applicable to materials and parts used in Supplier Articles, and carries out extensive research through trade associations and industry groups to develop detailed technical information on all known uses of the new regulated substances. The BOMcheck Regulatory Compliance Declaration tool uses this information to provide concise chemicals guidance which suppliers can rely on to identify materials and parts which are at risk of containing regulated substances. If the BOMcheck guidance indicates that the supplier parts are not at risk for a regulated substance (for example, because the substance is used in PVDF plastic and the supplier parts do not contain this type of plastic) then the supplier can claim compliance without additional efforts.

All substances in the BOMcheck Full Materials Declaration tool are colour coded to show the substances that are regulated today around the world and the substances that are at risk of becoming regulated in the next few years. The confidentiality tools enable suppliers to restrict access to their Regulatory Compliance Declarations and/or Full Materials Declarations to certain customers, and to add new customers to these confidentiality settings at any time. Suppliers can also attach test reports or other documentation to support their material declarations.

1. Product restrictions

Restriction of Certain Hazardous Substances (RoHS) Directive 2011/65/EU

The RoHS substance restrictions apply to every individual homogenous material in the part. BOMcheck is aligned with the IPC 1752A substance category list EUROHS-0508. The BOMcheck Full Materials Declaration tool provides the CAS numbers, common chemical names, synonyms and trade names for the substances which are included in each RoHS substance group.

Appendix A provides the list of exemptions published in Annex III of the RoHS Directive 2011/65/EU which remain valid for Medical Devices until at least 21 July 2021, with exceptions in red font. Appendix B provides the list of exemptions published in Annex IV of the RoHS Directive 2011/65/EU which remain valid for Medical Devices until at least 21 July 2021, with exceptions in red font. A declaration containing the worst case concentration of these substances is required so that compliance can be calculated when the exemption expires in the future. Note that these substance exemptions in the EU RoHS Directive do not provide any exemption from the product labelling requirements in China RoHS – the substances must be listed in the marking table.

Substance group	Maximum concentration of the substance in any individual homogenous material in the part
Cadmium/cadmium compounds	0.01% by weight (100 ppm) of homogeneous materials
Hexavalent Chromium compounds	0.1% by weight (1 000 ppm) of homogeneous materials
Lead/lead compounds	0.1% by weight (1 000 ppm) of homogeneous materials
Mercury/mercury compounds	0.1% by weight (1 000 ppm) of homogeneous materials
PBBs	0.1% by weight (1 000 ppm) of homogeneous materials
PBDEs	0.1% by weight (1 000 ppm) of homogeneous materials

RoHS substance restrictions amendment 1 (Directive 2011/65/EU, as amended by Directive (EU) 2015/863 of March 2015)

On 4 June 2015 the European Commission published Delegated Directive 2015/863 which officially adds four new substances and maximum concentration values in homogenous materials to Annex II of the RoHS Directive. Electrical and electronic equipment must comply with these additional substance restrictions from 22 July 2019, except for Medical Devices (Category 8) and Monitoring and Control Instruments (Category 9) which must comply with these additional substance restrictions from 22 July 2021.

Substance group	Maximum concentration of the substance in any individual homogenous material in the part
Bis(2-ethylhexyl) phthalate (DEHP)	0.1% by weight (1 000 ppm) of homogeneous materials
Butyl benzyl phthalate (BBP)	0.1% by weight (1 000 ppm) of homogeneous materials
Dibutyl phthalate (DBP)	0.1% by weight (1 000 ppm) of homogeneous materials
Diisobutyl phthalate (DIBP)	0.1% by weight (1 000 ppm) of homogeneous materials

Registration Evaluation Authorisation and Restriction of Chemicals (REACH) Regulation 1907/2006 (as amended)

REACH Candidate List substances found in Supplied Articles

REACH Article 33 requires all suppliers to inform their customers if the product they supply includes any article which contains any of the substances in the Candidate List in concentrations > 0.1% w/w of the article. An article is any item which has a special shape, surface or design which determines its function to a greater degree than its chemical composition (e.g. a screw, resistor, wire). Please note that this definition of an article may apply to individual components in your product. For further guidance on what is considered an article under the REACH Regulation please refer to the ECHA Guidance published at https://echa.europa.eu/documents/10162/23036412/articles_en.pdf

There are 219 Substances of Very High Concern (SVHCs) on the current REACH Candidate List published 8 July 2021 at http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp. The BOMcheck Substance List Working Group has determined that 116 of these SVHCs are not normally found in concentrations > 0.1% w/w in Supplied Articles. If parts and materials are manufactured using conventional industry processes, then the supplier can rely on the BOMcheck guidance and screen out these 116 SVHCs (BOMcheck will set the supplier's Regulatory Compliance Declaration to 'compliant' for these SVHCs). If any parts or materials are manufactured in a very unusual way (for example, using a secret process or unique ingredients) then the supplier must address each of the 219 SVHCs individually.

The CAS numbers published by ECHA for the 103 REACH Candidate List substances which can normally be found in Supplied Articles are included in the table below. Note that ECHA has not published CAS numbers for some REACH Candidate List Substances. The BOMcheck Full Materials Declaration tool provides the CAS numbers, common chemical names, synonyms and trade names for all of the REACH Candidate List substances. BOMcheck is aligned with the IPC 1752A substance category list EUREACH-0721 and the IPC 1752B substance category list EUREACH-0721.

REACH Candidate List Substances which can normally be found in Supplied Articles	CAS number(s) published by ECHA	Threshold
Included in REACH Candidate List on 28 October 2008		
Benzyl butyl phthalate (BBP)	85-68-7	0.1% by weight (1 000 ppm) of any article
Dibutyl phthalate (DBP)	84-74-2	0.1% by weight (1 000 ppm) of any article
Bis (2-ethylhexyl) phthalate (DEHP)	117-81-7	0.1% by weight (1 000 ppm) of any article
Hexabromocyclododecane (HBCDD) and all major diastereoisomers	25637-99-4, 3194-55-6, 134237-50-6,	0.1% by weight (1 000 ppm) of any article

	134237-51-7, 134237-52-8	
Shortchain chlorinated paraffins (C10 – C13)	85535-84-8	0.1% by weight (1 000 ppm) of any article
Cobalt dichloride (CoCl2)	7646-79-9	0.1% by weight (1 000 ppm) of any article
Diarsenic pentoxide	1303-28-2	0.1% by weight (1 000 ppm) of any article
Diarsenic trioxide	1327-53-3	0.1% by weight (1 000 ppm) of any article
Tributyl tin oxide (TBTO)	56-35-9	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 13 January 2010		
Tris (2-chloroethyl) phosphate (TCEP)	115-96-8	0.1% by weight (1 000 ppm) of any article
Lead chromate	7758-97-6	0.1% by weight (1 000 ppm) of any article
Lead chromate molybdate sulfate red (C.I. Pigment Red 104)	12656-85-8	0.1% by weight (1 000 ppm) of any article
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	1344-37-2	0.1% by weight (1 000 ppm) of any article
Diisobutyl phthalate (DIBP)	84-69-5	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 18 June 2010		
Disodium tetraborate, anhydrous	1303-96-4, 1330-43-4, 12179-04-3	0.1% by weight (1 000 ppm) of any article
Tetraboron disodium heptaoxide, hydrate	12267-73-1	0.1% by weight (1 000 ppm) of any article
Boric acid	10043-35-3, 11113-50-1	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 20 June 2011		
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)	68515-42-4	0.1% by weight (1 000 ppm) of any article
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP)	71888-89-6	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 19 December 2011		
2,2'-dichloro-4,4'-methylenedianiline	101-14-4	0.1% by weight (1 000 ppm) of any article
N,N-dimethylacetamide	127-19-5	0.1% by weight (1 000 ppm) of any article
Bis(2-methoxyethyl) phthalate	117-82-8	0.1% by weight (1 000 ppm) of any article
Bis(2-methoxyethyl) ether	111-96-6	0.1% by weight (1 000 ppm) of any article
Aluminosilicate Refractory Ceramic Fibres	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article

Zirconia Aluminosilicate Refractory Ceramic Fibres	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 18 June 2012		
Diboron trioxide	1303-86-2	0.1% by weight (1 000 ppm) of any article
1,2-bis(2-methoxyethoxy)ethane (TEGDME; triglyme)	112-49-2	0.1% by weight (1 000 ppm) of any article
1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME)	110-71-4	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 19 December 2012		
Bis(pentabromophenyl) ether (decabromodiphenyl ether; DecaBDE)	1163-19-5	0.1% by weight (1 000 ppm) of any article
1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0	0.1% by weight (1 000 ppm) of any article
Diisopentylphthalate	605-50-5	0.1% by weight (1 000 ppm) of any article
N-pentyl-isopentylphthalate	776297-69-9	0.1% by weight (1 000 ppm) of any article
Dibutyltin dichloride (DBTC)	683-18-1	0.1% by weight (1 000 ppm) of any article
Lead oxide sulfate	12036-76-9	0.1% by weight (1 000 ppm) of any article
[Phthalato(2-)]dioxotrilead	69011-06-9	0.1% by weight (1 000 ppm) of any article
Dioxobis(stearato)trilead	12578-12-0	0.1% by weight (1 000 ppm) of any article
Fatty acids, C16-18, lead salts	91031-62-8	0.1% by weight (1 000 ppm) of any article
Lead dinitrate	10099-74-8	0.1% by weight (1 000 ppm) of any article
Pentalead tetraoxide sulphate	12065-90-6	0.1% by weight (1 000 ppm) of any article
Sulfurous acid, lead salt, dibasic	62229-08-7	0.1% by weight (1 000 ppm) of any article
Tetralead trioxide sulphate	12202-17-4	0.1% by weight (1 000 ppm) of any article
Trilead dioxide phosphonate	12141-20-7	0.1% by weight (1 000 ppm) of any article
Orange lead (lead tetroxide)	1314-41-6	0.1% by weight (1 000 ppm) of any article
Lead cyanamidate	20837-86-9	0.1% by weight (1 000 ppm) of any article
Pyrochlore, antimony lead yellow	8012-00-8	0.1% by weight (1 000 ppm) of any article
4-Aminoazobenzene	60-09-3	0.1% by weight (1 000 ppm) of any article

1,2-Diethoxyethane	629-14-1	0.1% by weight (1 000 ppm) of any article
Silicic acid (H2Si2O5), barium salt (1:1), lead-doped	68784-75-8	0.1% by weight (1 000 ppm) of any article
N,N-dimethylformamide; dimethyl formamide	68-12-2	0.1% by weight (1 000 ppm) of any article
Lead titanium trioxide	12060-00-3	0.1% by weight (1 000 ppm) of any article
Lead titanium zirconium oxide	12626-81-2	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 20 June 2013		
4-Nonylphenol, branched and linear, ethoxylated *[substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]*	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article
Ammonium pentadecafluorooctanoate (APFO)	3825-26-1	0.1% by weight (1 000 ppm) of any article
Pentadecafluorooctanoic acid (PFOA)	335-67-1	0.1% by weight (1 000 ppm) of any article
Cadmium	7440-43-9	0.1% by weight (1 000 ppm) of any article
Cadmium oxide	1306-19-0	0.1% by weight (1 000 ppm) of any article
Dipentyl phthalate (DPP)	131-18-0	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 16 December 2013		
Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo] -5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	1937-37-7	0.1% by weight (1 000 ppm) of any article
Trixylyl phosphate	25155-23-1	0.1% by weight (1 000 ppm) of any article
Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	573-58-0	0.1% by weight (1 000 ppm) of any article
Dihexyl phthalate	84-75-3	0.1% by weight (1 000 ppm) of any article
Imidazolidine-2-thione; (2-imidazoline-2-thiol)	96-45-7	0.1% by weight (1 000 ppm) of any article
Cadmium sulphide	1306-23-6	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 16 June 2014		
1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	68515-50-4	0.1% by weight (1 000 ppm) of any article

Included in REACH Candidate List on 17 December 2014		
2-Benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	3846-71-7	0.1% by weight (1 000 ppm) of any article
2-(2H-Benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	25973-55-1	0.1% by weight (1 000 ppm) of any article
2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	15571-58-1	0.1% by weight (1 000 ppm) of any article
Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 15 June 2015		
1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with greater than or equal to 0.3% of dihexyl phthalate (EC No. 201-559-5)	68515-51-5, 68648-93-1	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 17 December 2015		
Perfluorononan-1-oic-acid and its sodium and ammonium salts	375-95-1, 21049-39-8, 4149-60-4	0.1% by weight (1 000 ppm) of any article
1,3-propanesultone	1120-71-4	0.1% by weight (1 000 ppm) of any article
2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	3864-99-1	0.1% by weight (1 000 ppm) of any article
2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	36437-37-3	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 20 June 2016		
Benzo[def]chrysene	50-32-8	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 12 January 2017		
4,4'-isopropylidenediphenol (bisphenol A)	80-05-7	0.1% by weight (1 000 ppm) of any article
Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts	3108-42-7, 335-76-2, 3830-45-3	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 7 July 2017		
Perfluorohexane-1-sulphonic acid and its salts (PFHxS)	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 15 January 2018		
Benz[a]anthracene	56-55-3, 1718-53-2	0.1% by weight (1 000 ppm) of any article

Cadmium hydroxide	21041-95-2	0.1% by weight (1 000 ppm) of any article
Chrysene	218-01-9, 1719-03-5	0.1% by weight (1 000 ppm) of any article
1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus"TM) [covering any of its individual anti- and syn-isomers or any combination thereof]	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 27 June 2018		
Benzo[ghi]perylene	191-24-2	0.1% by weight (1 000 ppm) of any article
Octamethylcyclotetrasiloxane (D4)	556-67-2	0.1% by weight (1 000 ppm) of any article
Decamethylcyclopentasiloxane (D5)	541-02-6	0.1% by weight (1 000 ppm) of any article
Dodecamethylcyclohexasiloxane (D6)	540-97-6	0.1% by weight (1 000 ppm) of any article
Terphenyl, hydrogenated	61788-32-7	0.1% by weight (1 000 ppm) of any article
Disodium octaborate	12008-41-2	0.1% by weight (1 000 ppm) of any article
Lead	7439-92-1	0.1% by weight (1 000 ppm) of any article
Dicyclohexyl phthalate (DCHP)	84-61-7	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 15 January 2019		
Benzo[k]fluoranthene	207-08-9	0.1% by weight (1 000 ppm) of any article
Fluoranthene	206-44-0, 93951-69-0	0.1% by weight (1 000 ppm) of any article
Phenanthrene	85-01-8	0.1% by weight (1 000 ppm) of any article
Pyrene	129-00-0, 1718-52-1	0.1% by weight (1 000 ppm) of any article
2,2-bis(4'-hydroxyphenyl)-4-methylpentane	6807-17-6	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 16 July 2019		
Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with greater than or equal to 0.1% w/w of 4-nonylphenol, branched and linear (4-NP)	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 16 January 2020		
Diisohexyl phthalate	71850-09-4	0.1% by weight (1 000 ppm) of any article
Perfluorobutane sulfonic acid (PFBS) and its salts	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article

Included in REACH Candidate List on 25 June 2020		
Dibutylbis(pentane-2,4-dionato-O,O')tin	22673-19-4	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 19 January 2021		
Bis(2-(2-methoxyethoxy)ethyl)ether	143-24-8	0.1% by weight (1 000 ppm) of any article
Dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 8 July 2021		
Medium-chain chlorinated paraffins (MCCP) [UVCB substances consisting of more than or equal to 80% linear chloroalkanes with carbon chain lengths within the range from C14 to C17]	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article
4,4'-(1-methylpropylidene)bisphenol	77-40-7	0.1% by weight (1 000 ppm) of any article
Orthoboric acid, sodium salt	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article

REACH substance restrictions applicable to Supplied Articles

REACH Article 67 contains over 75 different substance restrictions. However, the BOMcheck Substance List Working Group has screened out 53 of these substance restrictions because they are not relevant to parts and materials normally found in Supplied Articles. BOMcheck enables suppliers to declare against the following 22 restricted substances which can be present above the threshold levels in parts and materials normally found in Supplied Articles. Note that “No content permitted” means “The chemical substance is not allowed to be present in the material at any concentration level.”

The BOMcheck Regulatory Compliance Declaration tool provides information sheets for each individual substance restriction. The BOMcheck Full Materials Declaration tool provides the CAS numbers, common chemical names, synonyms and trade names for these restricted substances. BOMcheck is aligned with the IPC 1752A substance category list EUREACH-ARTICLE67-2018/2005 and the IPC 1752B substance category list IPC-1752B/EUREACH-ARTICLE67-2018/2005.

REACH restricted substances which can normally be found in Supplied Articles	**Threshold**
Bisphenol A in thermal paper	0.02% by weight (200 ppm) in thermal paper
Sum of Selected Phthalates Group 1 (DIBP, BBP, DBP, DEHP)	0.1% w/w of plasticised material
Asbestos fibres	No intentionally added content
Dibutyltin (DBT)	0.1% by weight of tin in a material
Monomethyl dibromodiphenyl methane	No intentionally added content
Monomethyl dichlorodiphenyl methane	No intentionally added content
Monomethyl tetrachlorodiphenyl methane	No intentionally added content
Polychlorinated terphenyls (PCTs)	No intentionally added content

1,2,4 Trichlorobenzene	Concentration must be < 0.1% w/w
Dimethyl Fumarate	0.00001% (0.1 ppm) w/w
Tri-substituted organostannic compounds	0.1 % by weight of tin in a material
Tar oils and creosotes	No content permitted in wood
Restrictions which apply to parts used in childcare products and toys	
Benzene	Concentration must be < 0.0005% w/w in toys
Dioctyltin (DOT) compounds	0.1% by weight of tin in a material
Selected Phthalates Group 2 (DIDP, DINP, DNOP)	0.1% w/w of plasticised material when used in toys and childcare articles which can be placed in the mouth
Any individual PAH compound – toys and childcare articles	0.00005% by weight (0.5 ppm) in plastic or rubber material in toys and childcare articles that come into direct, prolonged or repetitive skin or oral cavity contact
Restrictions which apply to parts containing leather or textiles	
Dioctyltin (DOT) compounds	0.1% by weight of tin in a material
Azo colourants containing certain amines	Not permitted in textile and leather articles which may come into direct and prolonged contact with skin
Tri (2,3-dibromo-propyl) phosphate	Not permitted in textile articles which may come into contact with skin
Tris (aziridinyl) phosphinoxide	Not permitted in textile articles which may come into contact with skin
Restrictions which apply to parts which come into contact with skin	
Any individual PAH compound	0.0001% by weight (1 ppm) in plastic or rubber material that come into direct, prolonged or repetitive skin or oral cavity contact
Nickel and nickel alloys	Must not be used in applications with direct and prolonged skin contact and where the rate of nickel release is > 0.5 micro gms per cm^2 per week
Restrictions which apply to parts which contain chemical products (liquids, gases, powders)	
Benzene	< 0.1% w/w in any substance or preparation
Pentachlorophenol	0.1% w/w in any substance or preparation
Nonylphenol and nonylphenol ethoxylates	Concentration must be < 0.1% w/w

Substances which are restricted or declarable by other legislation

BOMcheck includes substances which are restricted or declarable in legislation in all parts of the world, including North America, Asia Pacific and Europe. The BOMcheck Substance List Working Group has screened-out substance restrictions or declaration requirements which are not relevant to parts and materials normally found in Supplied Articles. BOMcheck enables suppliers to declare against the following substances which can be present above the threshold levels in parts and materials normally found in Supplied Articles. Note that “No content permitted” means “The chemical substance is not allowed to be present in the material at any concentration level.”

The BOMcheck Regulatory Compliance Declaration tool provides information sheets for each individual substance restriction or declaration requirement, including the applicable legislation and information on alternative substances. The BOMcheck Full Materials Declaration tool provides the CAS numbers, common chemical names, synonyms and trade names for these regulated substances.

Substances which can normally be found in Supplied Articles	**Threshold**
Phenol, Isopropylated Phosphate (3:1) (PIP 3:1)	No intentionally added content
Bisphenol S in thermal paper	0.02% by weight (200 ppm) in thermal paper
Perfluorooctanoic acid and its salts	0.0000025% by weight (25 ppb) of any article
Formaldehyde	No intentionally added content in composite wood products or components (plywood, particle board and MDF) and textiles
Pentachlorophenol (PCP)	No intentionally added content
Polychlorinated and polybrominated dioxins and furans	No intentionally added content
Radioactive substances	No intentionally added content
PFOS	0.1% w/w
Polybrominated diphenyl ethers (PBDEs)	0.05% (500 ppm) by weight in a material
HBCDD (Hexabromocyclododecane)	0.01% (100 ppm) by weight in a material
Shortchain chlorinated paraffins (C10 – C13)	0.15% (1 500 ppm) by weight in a material
Polychlorinated biphenyls (PCBs)	No intentionally added content
Polychlorinated naphthalenes	No intentionally added content
Restrictions which apply to parts used in childcare products and toys	
Flame retardant chemicals	0.1% by weight (1 000 ppm) in a material in toys and childcare products
Di-n-pentyl phthalate (DPENP)	0.1% by weight (1 000 ppm) in a material in toys and childcare products
Di-n-hexyl phthalate (DHEXP)	0.1% by weight (1 000 ppm) in a material in toys and childcare products
Dicyclohexyl phthalate (DCHP)	0.1% by weight (1 000 ppm) in a material in toys and childcare products
Diisononyl phthalate (DINP)	0.1% by weight (1 000 ppm) in a material in toys and childcare products
Tris (2-chloroethyl) phosphate (TCEP)	No content permitted in toys and childcare products
Tris(2-chloro-1-methylethyl) phosphate (TCPP)	No content permitted in toys and childcare products
Tris (1,3-dichloro-2-propyl) phosphate (TDCPP)	No content permitted in toys and childcare products
Lead/lead compounds in consumer products designed or intended primarily for children 12 years of age or younger	0.01% w/w in accessible parts in toys and childcare articles

Lead/lead compounds in paint and similar surface coatings of toys and other articles intended to be used by children	0.009% w/w in paint in toys and childcare articles
Restrictions which apply to parts used in medical devices	
Bisphenol A	Declare if manufactured from raw materials using BPA or derived from BPA, and if used in medical devices and part comes into contact with patient or patient fluids
Latex	No intentionally added content in medical devices
CMR 1A and 1B substances and endocrine disrupting substances	0.1% by weight (1 000ppm) in any material which has invasive contact with the patient, or any material which transports or stores fluids or gases which contact the patient
Restrictions which apply to parts which come into contact with food	
Bisphenol A	No content permitted in products which contact with food
Restrictions which apply to parts which contain chemical products (liquids, gases, powders)	
Ozone depleting substances	No intentionally added content
Fluorinated Greenhouse Gases (PFC, SF6, HFC)	No content permitted
Restrictions which apply to parts which contain textiles	
Flame retardant chemicals	0.1% by weight (1 000 ppm) in a material in textiles

Batteries substance restrictions

The following restrictions apply to all batteries. The BOMcheck Full Materials Declaration tool provides the CAS numbers, common chemical names, synonyms and trade names for these restricted substances.

Substances	Maximum concentration in the battery
Cadmium/cadmium compounds	0.001 % by weight (10 ppm) of battery
Mercury/mercury compounds	0.0001% by weight (1 ppm) of battery
Lead/lead compounds	0.004% by weight (40 ppm) of battery
Perchlorates	0.0000006% by weight (6 ppb) of battery

Proposition 65

Dr Paul Goodman at RINA Consulting carried out a screening of the 900 plus substances on the Proposition 65 list and identified 107 that may be relevant to component parts of Supplied Articles (in other words, any component of a manufactured product which is not defined as a substance or preparation (mixture) under the REACH regulation). Dr Goodman's screening shows that 39 of these substances do not require "safe harbour" warnings. This leaves 68 substances which may be found in component parts of Supplied Articles and may require "safe harbour" warnings.

BOMcheck's assessment of Dr Goodman's screening has identified that 28 of these 68 substances are already regulated under RoHS, REACH substance restrictions, POPs regulation or REACH Candidate List in BOMcheck. In other words, if supplier parts are already compliant to the RoHS, REACH substance

restrictions, POPs regulation and REACH Candidate List in BOMcheck then there are only 40 new substances that suppliers need to assess for Proposition 65. The detailed screening assessment is published inside BOMcheck and reduces the time and cost for Proposition 65 compliance by 97%.

If the finished product includes a supplier part which contains Proposition 65 substance(s) then you need to assess whether the user could be exposed to the part during normal use of the product. If yes, then you should provide an appropriate "safe harbour" warning and communicate the name of one Proposition 65 substance for each endpoint (for example, one carcinogen of the Proposition 65 substance(s) are listed for cancer).

Proposition 65 substances which can normally be found in Supplied Articles	**Threshold**
Indium tin oxide	0.1% by weight (1 000 ppm) of any material
Lead and Lead Compounds	0.009% (90 ppm) of any material
Bisphenol A (BPA)	0.0003% (3 ppm) of any material
Phthalate plasticisers	
Diisononyl phthalate (DiNP)	No intentionally added content
Di-isodecyl phthalate (DIDP)	No intentionally added content
Di-n-hexyl phthalate (DnHP)	No intentionally added content
Flame retardants and plasticisers	
Tris(1,3-dichloro-2-propyl) Phosphate (TDCPP)	0.0025% by weight (25 ppm) of any material
Tris(2-chloroethyl) Phosphate	0.0025% by weight (25 ppm) of any material
Tris(2,3-dibromopropyl)phosphate	0.0025% by weight (25 ppm) of any material
Flame retardants	
Molybdenum Trioxide	0.1% by weight (1 000 ppm) of any material
Antimony Oxide (Antimony trioxide)	0.1% by weight (1 000 ppm) of any material
Tetrabromobisphenol A	0.1% by weight (1 000 ppm) of any material
2,2-Bis(bromomethyl)-1,3-propanediol	0.1% by weight (1 000 ppm) of any material
Mirex	0.1% by weight (1 000 ppm) of any material
UV protection agents	
Benzophenone	0.1% by weight (1 000 ppm) of any material
Colourants	
Benzidine-based Dyes	0.1% by weight (1 000 ppm) of any material
3,3'-Dimethoxybenzidine-based dyes metabolized to 3,3'-dimethoxybenzidine	0.1% by weight (1 000 ppm) of any material
3,3'-Dimethylbenzidine-based dyes metabolized to 3,3'-dimethylbenzidine	0.1% by weight (1 000 ppm) of any material

D&C Orange No. 17	0.1% by weight (1 000 ppm) of any material
1-Amino-2,4-dibromoanthraquinone	0.1% by weight (1 000 ppm) of any material
1-Amino-2-methylanthraquinone	0.1% by weight (1 000 ppm) of any material
Direct Blue 6 (Technical Grade)	0.1% by weight (1 000 ppm) of any material
Direct Brown 95 (Technical Grade)	0.1% by weight (1 000 ppm) of any material
Disperse Blue 1	0.1% by weight (1 000 ppm) of any material
Impurities in extender oils and black colourants	
Naphthalene	0.0001% by weight (1 ppm) of any material
REACH Article 67 substance restrictions which may be found in hardware and electrical and electronic equipment (Regulation 1907/2006)	
Any individual PAH compound	0.0001% by weight (1 ppm) in plastic or rubber material that come into direct, prolonged or repetitive skin or oral cavity contact
Asbestos	No intentionally added content
Azocolourants and azodyes which form certain aromatic amines	Not permitted in textile and leather articles which may come into direct and prolonged contact with skin
Nickel and nickel alloys	Must not be used in applications with direct and prolonged skin contact and where the rate of nickel release is > 0.5 micro gms per cmÂ² per week
Tar oils and creosotes	No content permitted in wood and wooden materials
RoHS substance restrictions (Directive 2011/65/EU)	
Cadmium/cadmium compounds	0.01% by weight (100 ppm) of homogeneous materials
Hexavalent Chromium	0.1% by weight (1 000 ppm) of homogenous materials
Mercury/Mercury compounds	0.1% by weight (1 000 ppm) of homogenous materials
PBBs	0.1% by weight (1 000 ppm) of homogenous materials
PBDEs	0.1% by weight (1 000 ppm) of homogenous materials
REACH candidate list substances (Regulation 1907/2006)	
4,4'-isopropylidenediphenol [Bisphenol A; BPA]	0.1% by weight (1 000 ppm) of any article
DEHP (Di(2-ethylhexyl) phthalate)	0.1% by weight (1 000 ppm) of any article
DBP (Dibutyl phthalate)	0.1% by weight (1 000 ppm) of any article
BBP (Benzylbutyl phthalate)	0.1% by weight (1 000 ppm) of any article
SCCP (Short-chained chlorinated paraffins)	0.1% by weight (1 000 ppm) of any article
Direct Black 38 (Technical Grade)	0.1% by weight (1 000 ppm) of any article
4-Aminoazobenzene	0.1% by weight (1 000 ppm) of any article
Persistent Organic Pollutants Regulation 850/2004	

Perfluorooctanoic acid and its salts	0.0000025% by weight (25ppb) of any article
PFOS (Perfluorooctane Sulfonates)	0.1% by weight (1 000 ppm) of any material
Polychlorinated biphenyls (PCBs)	No intentionally added content

Industry restricted and declarable substances

The following substances are restricted by leading OEMs to comply with product safety standards in Germany and to reduce severe environmental or health and safety impacts. Suppliers can check the information pages in the BOMcheck tool to find out which OEMs require their suppliers to comply with particular industry substance restrictions.

Substances which can normally be found in Supplied Articles	**Threshold**
Beryllium and Beryllium compounds	0.1% by weight (1 000 ppm) of any material
Brominated flame retardants (other than PBBs, PBDEs or HBCDD)	Declare if > 0.1% w/w total bromine content from BFRs
Brominated flame retardants (other than PBBs, PBDEs or HBCDD)	Declare if > 0.09% total bromine content from BFRs in printed wiring board laminate
Chlorinated flame retardants	Declare if > 0.1% w/w total chlorine content from CFRs
Chlorinated flame retardants	Declare if > 0.09% total chlorine content from CFRs in printed wiring board laminate
PVC and PVC copolymers	Declare if > 0.1% w/w total chlorine content from PVC
Antimony trioxide in plastic materials	Declare if > 0.1% w/w in plastic parts
Phthalates	Declare if > 0.1% w/w
Restrictions which apply to parts containing leather or textiles	
Alkylphenol and alkylphenol ethoxylates	0.01% by weight (100 ppm) in textile and leather articles
Restrictions which apply to parts used in lamps and lamp ballasts	
Antimony compounds in glass	0.1% w/w in glass in lamps
Arsenic compounds in glass	0.1% w/w in glass in lamps
Polycyclic Aromatic Hydrocarbons (PAH)	0.005% in potting material in electronic or magnetic ballast for lamps
Restrictions which apply to parts which come into contact with skin	
Azo Colourants	30 ppm if part comes into contact with skin
Benzoapyrene in contact with skin	The limits for different applications are provided in the information sheet
Sum of all PAHs	The limits for different applications are provided in the information sheet

2. Packaging restrictions

Packaging Directive 94/62/EC

Substances	Maximum concentration in the supplied packaging
Sum of all heavy metals (Cd, Hg, Cr(VII) and Pb)	0.01% in the supplied packaging

Registration Evaluation Authorisation and Restriction of Chemicals (REACH) Regulation 1907/2006 (as amended)

REACH Candidate List substances found in packaging

REACH Article 33 requires all suppliers to inform their customers if the product they supply includes any article which contains any of the substances in the Candidate List in concentrations > 0.1% w/w of the article. An article is a product which has a special shape, surface or design which determines its function to a greater degree than its chemical composition. Please note that this definition of an article may apply to individual components in your product. For further guidance on what is considered an article under the REACH Regulation please refer to the ECHA Guidance published at http://echa.europa.eu/documents/10162/13632/articles_en.pdf. The REACH regulation also applies to packaging.

There are 219 Substances of Very High Concern (SVHCs) on the current REACH Candidate List published 8 July 2021. The BOMcheck Substance List Working Group has determined that 179 of these SVHCs are not normally found in concentrations > 0.1% w/w in packaging. BOMcheck enables suppliers to screen-out these 179 substances and instead requires suppliers to declare against the following 40 substances which can be present in concentrations > 0.1% w/w in packaging articles.

REACH Candidate List Substances which can normally be found in packaging	CAS number(s) published by ECHA	Threshold
Included in REACH Candidate List on 28 October 2008		
Benzyl butyl phthalate (BBP)	85-68-7	0.1% by weight (1 000 ppm) of any article
Dibutyl phthalate (DBP)	84-74-2	0.1% by weight (1 000 ppm) of any article
Bis (2-ethylhexyl) phthalate (DEHP)	117-81-7	0.1% by weight (1 000 ppm) of any article
Hexabromocyclododecane (HBCDD) and all major diastereoisomers	25637-99-4, 3194-55-6, 134237-50-6, 134237-51-7, 134237-52-8	0.1% by weight (1 000 ppm) of any article
Cobalt dichloride (CoCl2)	7646-79-9	0.1% by weight (1 000 ppm) of any article
Tributyl tin oxide (TBTO)	56-35-9	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 13 January 2010		
Tris (2-chloroethyl) phosphate (TCEP)	115-96-8	0.1% by weight (1 000 ppm) of any article
Diisobutyl phthalate (DIBP)	84-69-5	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 18 June 2010		
Disodium tetraborate, anhydrous	1303-96-4, 1330-43-4, 12179-04-3	0.1% by weight (1 000 ppm) of any article

Tetraboron disodium heptaoxide, hydrate	12267-73-1	0.1% by weight (1 000 ppm) of any article
Boric acid	10043-35-3, 11113-50-1	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 20 June 2011		
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)	68515-42-4	0.1% by weight (1 000 ppm) of any article
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP)	71888-89-6	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 19 December 2011		
2,2'-dichloro-4,4'-methylenedianiline	101-14-4	0.1% by weight (1 000 ppm) of any article
Bis(2-methoxyethyl) phthalate	117-82-8	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 18 June 2012		
Diboron trioxide	1303-86-2	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 19 December 2012		
Bis(pentabromophenyl) ether (decabromodiphenyl ether; DecaBDE)	1163-19-5	0.1% by weight (1 000 ppm) of any article
1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0	0.1% by weight (1 000 ppm) of any article
Diisopentylphthalate	605-50-5	0.1% by weight (1 000 ppm) of any article
N-pentyl-isopentylphthalate	776297-69-9	0.1% by weight (1 000 ppm) of any article
Dibutyltin dichloride (DBTC)	683-18-1	0.1% by weight (1 000 ppm) of any article
Lead oxide sulfate	12036-76-9	0.1% by weight (1 000 ppm) of any article
[Phthalato(2-)]dioxotrilead	69011-06-9	0.1% by weight (1 000 ppm) of any article
Dioxobis(stearato)trilead	12578-12-0	0.1% by weight (1 000 ppm) of any article
Fatty acids, C16-18, lead salts	91031-62-8	0.1% by weight (1 000 ppm) of any article
Lead dinitrate	10099-74-8	0.1% by weight (1 000 ppm) of any article
Pentalead tetraoxide sulphate	12065-90-6	0.1% by weight (1 000 ppm) of any article
Sulfurous acid, lead salt, dibasic	62229-08-7	0.1% by weight (1 000 ppm) of any article
Tetralead trioxide sulphate	12202-17-4	0.1% by weight (1 000 ppm) of any article

Trilead dioxide phosphonate	12141-20-7	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 20 June 2013		
Dipentyl phthalate (DPP)	131-18-0	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 16 December 2013		
Dihexyl phthalate	84-75-3	0.1% by weight (1 000 ppm) of any article
Imidazolidine-2-thione; (2-imidazoline-2-thiol)	96-45-7	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 16 June 2014		
1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	68515-50-4	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 17 December 2014		
2-Benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	3846-71-7	0.1% by weight (1 000 ppm) of any article
2-(2H-Benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	25973-55-1	0.1% by weight (1 000 ppm) of any article
2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	15571-58-1	0.1% by weight (1 000 ppm) of any article
Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)	No CAS number(s) provided	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 15 June 2015		
1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with greater than or equal to 0.3% of dihexyl phthalate (EC No. 201-559-5)	68515-51-5, 68648-93-1	0.1% by weight (1 000 ppm) of any article
Included in REACH Candidate List on 17 December 2015		
2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	3864-99-1	0.1% by weight (1 000 ppm) of any article
2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	36437-37-3	0.1% by weight (1 000 ppm) of any article

REACH substance restrictions applicable to packaging articles

REACH Article 67 contains over 65 different substance restrictions. However, the BOMcheck Substance List Working Group has screened-out 62 of these substance restrictions because they are not relevant to parts and materials normally found in packaging articles. BOMcheck enables suppliers to declare against the following 3 restricted substances which can be present above the threshold levels in packaging articles.

Substances which can normally be found in packaging articles	Threshold
Arsenic compounds	No intentionally added content
Formaldehyde	0.1% in the supplied packaging
Dimethyl Fumarate	0.00001% (0.1 ppm) w/w

Industry restricted and declarable substances

These substances are restricted by leading OEMs to comply with retailer restrictions on PVC in packaging and use of EPS in consumer products. Suppliers can check the information pages in the BOMcheck tool to find out which OEMs require their suppliers to comply with particular industry substance restrictions.

Substances which can be found in packaging articles	Maximum concentration of the substance in the supplied packaging
PVC	0.1% in supplied packaging
Expanded polystyrene (EPS) and other polymeric foam materials (e.g, EPP, EPE, EVA) as shock absorber buffers enclosing the product (excluding thin foam sheets and foam bags) inside any consumer product packaging	Not permitted

Appendix A: Exemptions published in Annex III to the RoHS Directive (2011/65/EU) which remain valid for Medical Devices at July 2021, with the exceptions in red font

Number	Description
1(a)	Mercury in single capped (compact) fluorescent lamps not exceeding (per burner):For general lighting purposes < 30 W: 2.5 mg
1(b)	Mercury in single capped (compact) fluorescent lamps not exceeding (per burner):For general lighting purposes ≥ 30 W and < 50 W; 3.5 mg
1(c)	Mercury in single capped (compact) fluorescent lamps not exceeding (per burner):For general lighting purposes ≥ 50 W and < 150 W; 5 mg
1(d)	Mercury in single capped (compact) fluorescent lamps not exceeding (per burner):For general lighting purposes ≥ 150 W; 15 mg
1(e)	Mercury in single capped (compact) fluorescent lamps not exceeding (per burner):For general lighting purposes with circular or square structural shape and tube diameter ≤ 17 mm ; 7 mg
1(f)	Mercury in single capped (compact) fluorescent lamps not exceeding (per burner):For special purposes: 5 mg
1(g)	Mercury in single capped (compact) fluorescent lamps not exceeding (per burner):For general lighting purposes < 30 W with a lifetime equal or above 20,000 h: 3.5 mg.
2(a)(1)	Mercury in double-capped linear fluorescent lamps for generation lighting purposes not exceeding (per lamp):Tri-band phosphor with normal lifetime and a tube diameter < 9 mm (e.g. T2) : 4 mg
2(a)(2)	Mercury in double-capped linear fluorescent lamps for generation lighting purposes not exceeding (per lamp):Tri-band phosphor with normal lifetime and a tube diameter ≥ 9 mm and ≤ 17 mm (e.g. T5): 3 mg
2(a)(3)	Mercury in double-capped linear fluorescent lamps for generation lighting purposes not exceeding (per lamp):Tri-band phosphor with normal lifetime and a tube diameter > 17 mm and ≤ 28 mm (e.g. T8): 3.5 mg
2(a)(4)	Mercury in double-capped linear fluorescent lamps for generation lighting purposes not exceeding (per lamp):Tri-band phosphor with normal lifetime and a tube diameter > 28 mm (e.g. T12):3.5 mg
2(a)(5)	Mercury in double-capped linear fluorescent lamps for generation lighting purposes not exceeding (per lamp):Tri-band phosphor with long lifetime (≥ 25,000 h): 5 mg
2(b)(3)	Mercury in other fluorescent lamps not exceeding (per lamp):Non-linear tri-band phosphor lamps with tube diameter > 17 mm (e.g. T9) : 15 mg
2(b)(4)	Mercury in other fluorescent lamps not exceeding (per lamp):Lamps for other general lighting and special purposes (e.g. induction lamps) : 15 mg
3(a)	Mercury in cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFL and EEFL) for special purposes not exceeding (per lamp): Short length (≤ 500 mm) : 3.5 mg
3(b)	Mercury in cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFL and EEFL) for special purposes not exceeding (per lamp): Medium length (> 500 mm and ≤ 1,500 mm) : 5 mg
3(c)	Mercury in cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFL and EEFL) for special purposes not exceeding (per lamp): Long length (> 1,500 mm) : 13 mg
4(a)	Mercury in other low pressure discharge lamps (per lamp) : 15 mg
4(b)-I	Mercury in High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner) in lamps with improved colour rendering index Ra > 60: P ≤ 155 W : 30 mg
4(b)-II	Mercury in High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner) in lamps with improved colour rendering index Ra > 60: 155 W < P ≤ 405 W : 40 mg
4(b)-III	Mercury in High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner) in lamps with improved colour rendering index Ra > 60: P > 405 W : 40 mg
4(c)-I	Mercury in High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner): P ≤ 155 W : 25 mg

4(c)-II	Mercury in High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner): 155 W < P ≤ 405 W : 30 mg
4(c)-III	Mercury in High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner): P > 405 W : 40 mg
4(e)	Mercury in metal halide lamps (MH)
4(f)	Mercury in other discharge lamps for special purposes not specially mentioned in this Annex
5(b)	Lead in glass of fluorescent tubes not exceeding 0.2% by weight
6(a)	Lead as an alloying element in steel for machining purposes and in galvanized steel containing up to 0.35% lead by weight
6(b)	Lead as an alloying element in aluminum containing up to 0.4% lead by weight
6(c)	Copper alloy containing up to 4% lead by weight
7(a)	Lead in high melting temperature type solders (i.e. lead-based alloys containing 85% by weight or more lead)
7(c)-I	Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound
7(c)-II	Lead in dielectric ceramic in capacitors for a rated voltage of 125 V AC or 250 V DC or higher
8(b)	Cadmium and its compounds electrical contacts
13(a)	Lead in white glasses used for optical applications
13(b)	Cadmium and lead in filter glasses and glasses used for reflectance standards
15	Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages
18(b)	Lead as activator in the fluorescent powder (1% lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP (BaSi2O5:Pb)
18(b)-I	Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps containing phosphors such as BSP (BaSi2O5:Pb) when used in medical phototherapy equipment
24	Lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors
29	Lead bound in crystal glass as defined in Annex I (Categories 1, 2, 3 and 4) of Council Directive 69/493/EEC
32	Lead oxide in seal frit used for making window assemblies for Argon and Krypton laser tubes
34	Lead in cermet-based trimmer potentiometer elements
39(a)	Cadmium selenide in downshifting cadmium-based semiconductor nanocrystal quantum dots for use in display lighting applications (less than 0.2 microgram Cd per mm2 of display screen area)
42	Lead in bearings and bushes of diesel or gaseous fuel powered internal combustion engines applied in non-road professional use equipment: with engine total displacement greater than or equal to 15 litres; or with engine total displacement less than 15 litres and the engine is designed to operate in applications where the time between signal to start and full load is required to be less than 10 seconds; or regular maintenance is typically performed in a harsh and dirty outdoor environment, such as mining, construction, and agriculture applications
43	Bis(2-ethylhexyl) phthalate in rubber components in engine systems, designed for use in equipment that is not intended solely for consumer use and provided that no plasticised material comes into contact with human mucous membranes or into prolonged contact with human skin and the concentration value of bis(2-ethylhexyl) phthalate does not exceed: (a) 30 % by weight of

	the rubber for (i) gasket coatings; (ii) solid-rubber gaskets; or (iii) rubber components included in assemblies of at least three components using electrical, mechanical or hydraulic energy to do work, and attached to the engine. (b) 10 % by weight of the rubber for rubber-containing components not referred to in point (a). For the purposes of this entry, “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
44	Lead in solder of sensors, actuators, and engine control units of combustion engines within the scope of Regulation (EU) 2016/1628 of the European Parliament and of the Council (*) , installed in equipment used at fixed positions while in operation which is designed for professionals, but also used by non-professional users

Appendix B: Exemptions published in Annex IV to the RoHS Directive (2011/65/EU) which remain valid for Medical Devices at July 2021, with exceptions in red font

Number	Description
1	Lead, cadmium and mercury in detectors for ionising radiation
1a	Lead and cadmium in ion selective electrodes including glass of pH electrodes.
1b	Lead anodes in electrochemical oxygen sensors.
1c	Lead, cadmium and mercury in infra-red light detectors.
2	Lead bearings in X-ray tubes.
3	Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate.
5	Lead in shielding for ionising radiation.
11	Lead in alloys as a superconductor and thermal conductor in MRI.
12	Lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR (Nuclear Magnetic Resonance) or FTMS (Fourier Transform Mass Spectrometer) detectors. Expires on 30 June 2021.
13	Lead in counterweights.
14	Lead in single crystal piezoelectric materials for ultrasonic transducers.
15	Lead in solders for bonding to ultrasonic transducers.
17	Lead in solders in portable emergency defibrillators.
26	Lead in the following applications that are used durably at a temperature below – 20 °C under normal operating and storage conditions: (a) solders on printed circuit boards; (b) termination coatings of electrical and electronic components and coatings of printed circuit boards; (c) solders for connecting wires and cables; (d) solders connecting transducers and sensors. Lead in solders of electrical connections to temperature measurement sensors in devices which are designed to be used periodically at temperatures below – 150 °C.
27	Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors, which are used in (a) magnetic fields within the sphere of 1 m radius around the isocenter of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere, or (b) magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy.
29	Lead in alloys, as a superconductor or thermal conductor, used in cryo-cooler cold heads and/or in cryo-cooled cold probes and/or in cryo-cooled equipotential bonding systems, in medical devices (category 8) and/or in industrial monitoring and control instruments.
31a	Lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer. **Expires on: (a) 21 July 2021 for the use in medical devices other than in vitro diagnostic medical devices; (b) 21 July 2023 for the use in in vitro diagnostic medical devices; (c) 21 July 2024 for the use in electron microscopes and their accessories.**
35	Mercury in cold cathode fluorescent lamps for back-lighting liquid crystal displays, not exceeding 5 mg per lamp, used in industrial monitoring and control instruments placed on the market before 22 July 2017. **Expires on 21 July 2024.**
36	Lead used in other than C-press compliant pin connector systems for industrial monitoring and control instruments. **Expires on 31 December 2020**. May be used after that date in spare parts for industrial monitoring and control instruments placed on the market before 1 January 2021.
37	Lead in platinized platinum electrodes used for conductivity measurements where at least one of the following conditions applies: (a) wide-range measurements with a conductivity range covering more than 1 order of magnitude (e.g. range between 0.1 mS/m and 5 mS/m) in laboratory applications for unknown concentrations; (b) measurements of solutions where an accuracy of +/– 1 % of the sample range and where high corrosion resistance of the electrode are required for any of the following: (i)

	solutions with an acidity < pH 1; (ii) solutions with an alkalinity > pH 13; (iii) corrosive solutions containing halogen gas; (c) measurements of conductivities above 100 mS/m that must be performed with portable instruments.
39	Lead in micro-channel plates (MCPs) used in equipment where at least one of the following properties is present: (a) a compact size of the detector for electrons or ions, where the space for the detector is limited to a maximum of 3 mm/MCP (detector thickness + space for installation of the MCP), a maximum of 6 mm in total, and an alternative design yielding more space for the detector is scientifically and technically impracticable; (b) a two-dimensional spatial resolution for detecting electrons or ions, where at least one of the following applies: (i) a response time shorter than 25 ns; (ii) a sample detection area larger than 149 mm2; (iii) a multiplication factor larger than 1.3 × 103. (c) a response time shorter than 5 ns for detecting electrons or ions; (d) a sample detection area larger than 314 mm2 for detecting electrons or ions; (e) a multiplication factor larger than 4.0 × 107. **The exemption expires on the following dates: (a) 21 July 2021 for medical devices and monitoring and control instruments; (b) 21 July 2023 for in-vitro diagnostic medical devices; (c) 21 July 2024 for industrial monitoring and control instruments.**
40	Lead in dielectric ceramic in capacitors for a rated voltage of less than 125 V AC or 250 V DC for industrial monitoring and control instruments. **Expires on 31 December 2020**. May be used after that date in spare parts for industrial monitoring and control instruments placed on the market before 1 January 2021.
41	Lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases.
42	Mercury in electric rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (greater than 50 MHz) modes of operation.
43	Cadmium anodes in Hersch cells for oxygen sensors used in industrial monitoring and control instruments, where sensitivity below 10 ppm is required. **Expires on 15 July 2023.**
44	Cadmium in radiation tolerant video camera tubes designed for cameras with a centre resolution greater than 450 TV lines which are used in environments with ionising radiation exposure exceeding 100 Gy/hour and a total dose in excess of 100kGy.