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CERTIFICATE OF RoHS3, REACH COMPLIANCE & MEDICAL DEVICE DIRECTIVE AS OF June 25, 2020

O-Rings West declares, that all products and materials manufactured/or delivered to our customers are in conformity with the July 21st 2011 RoHS Directive 2011/65/EU and the June 4, 2015 new Directive (EU) 2015/863 to amend Annex II to EU RoHS 2 (Directive 2011/65/EU) to add 4 phthalates onto the list of restricted substances, which total 10 hazardous substances.

Substances and Limits in Homogenous Materials

Cadmium (Cd): 0.01%	Mercury: 0.1%
Lead (Pb): 0.1%	Hexavalent chromium (C46+): 0.1%
Polybrominated biphenyls (PBB): 0.1%	Polybrominated diphenyl ethers (PBDE): 0.1%
Bis (2-Ethylhexyl) phthalate (DEHP): 0.1% (added in 2015)	
Benzyl butyl phthalate (BBP): 0.1% (added in 2015)	
Dibutyl phthalate (DBP): 0.1% (added in 2015)	
Diisobutyl phthalate (DIBP): 0.1% (added in 2015)	

The company also declares conformity with regulation 1907/2006 of the European Parliament and the Council, concerning registration, evaluation, authorization and restriction of chemicals (REACH) including the December 17th, 2015 ECHA amendment to the list of substances of very high concern (SVHC).

EU REACH has added one new SVHC to the list as of June 20, 2016 (Benzo(def)chrysene, EC # 200-028-5, CSA # 50-32-8).

EU REACH has added four new SVHC to the list as of January 12, 2017 (isopropylidenediphenol, nonadecafluorodecanoic acid, dimethylpropyl, heptylphenol) and perfluorooctanesulfonic acid. The Candidate of (SVHCs) for authorization now contains 173 substances.

The company also declares conformity with regulation Medical Device Directive 93/42/EC as amended by 2007/47/EEC (Tissues of Any Type, Including Animal) and Medical Device Directive 93/42/EEC as amended by 2007/47/EC (Human Blood Derivatives).

O-Rings West declares that it complies with the "Limits on the PAH Content of Consumer Articles Regulation EU 1272/2013 amending REACH Annex XVII".

The European Union (EU) Commission has enacted the above referenced regulation which limits the content of the following eight polycyclic aromatic hydrocarbons (PAHs) in the accessible plastic or rubber parts of certain articles placed on the EU market from 27 December 2015 onward:

♦Benzo[a]pyrene	<1ppm	♦Benzo[b]flouranthene	<1ppm
♦Benzo[e]pyrene	<1ppm	♦Benzo[f]flouranthene	<1ppm
♦Benzo[a]anthracene	<1ppm	♦Benzo[k]flouranthene	<1ppm
♦Chrysene	<1ppm	♦Dibenzo[a,h]anthracene	<1ppm

On July 10, 2017, ECHA added:

Perfluorohexane-1-sulphonic acid and its salts (PFHxS)

On January 15, 2018 ECHA addeed:

♦Benz[a]anthracene	<1ppm	♦Cadmium carbonate	<1ppm
♦Cadmium hydroxide	<1ppm	♦Cadmium nitrate	<1ppm
♦Chrysene	<1ppm	♦Dodecachloropentcyclo	<1ppm
♦Reaction products of 1,3, 4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptyphenol, branched and linear		<1ppm	

On April 17, 2018 ECHA added:

♦Dicyclohexl phthalate	<1ppm		
♦Benzene-1,2,4 tricarboxylic acid 1,2 anhydride (tirmellitic anhydride)(TMA)		<1ppm	

On June 27, 2018 ECHA added:

♦ Benzo[ghi]perylene	♦ Ethylenediamine
♦ Decamethylcyclopentasiloxane (D5)	♦ Lead
♦ Disodium octaborate	♦ Octamethylcyclotetrasiloxane(D4)
♦ Dodecamethylcyclohexasiloxane(D6)	♦ Terphenyl, hydrogenated

On January 15, 2019 ECHA added:

♦ Methylpentane	♦ Benzo[k]fluoranthene
♦ Fluoranthene	♦ Phenanthrene
♦ (phenylmethylene)bicyclo[2.2.1]heptan-2-one	♦ Pyrene

On July 16, 2019 ECHA added:

- ◆ Tetrafluoro-2-(heptafluoropropoxy)propionic acid
- ◆ Methoxyethyl acetate
- ◆ Tris(4-nonylphenyl) phosphite (TNPP) with $\geq 0.1\%$ w/w of 4-nonylphenol, branched and linear
- ◆ Tert-butylphenol

On January 16, 2020 ECHA added:

- ◆ Perfluorobutane sulfonic acid
- ◆ 2-Methyl-1-(4-methylthiophenyl)2-morpholinopropan-1
- ◆ Diisohexyl phthalate
- ◆ 2-Benzyl-2-dimethylamio-4 morpholinobutyrophenone

On June 25, 2020 ECHA added:

- ◆ Vinylimidazole
- ◆ Dibutylbis(pentane-2-4-dionato-O,O')tin
- ◆ methylimidazole
- ◆ Butyl 4-hydroxybenzoate

On January 19, 2021 ECHA added:

- ◆ Dioctyltin dilaurate; stannane dioctyl
- ◆ Bis(2-(methoxyethoxy) ethyl)ether

The total SVHC candidate list is now 211.

O-Rings West, Inc. confirms that we are RoHS3 compliant.

John McBrady

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