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MATERIAL AND REGULATORY INFORMATION SUMMARY

Silcon® Med-X - Platinum Cured Medical Grade Silicone Tubing; Shore 50A - Product Series 284

Legislation	Compliant	Note	Date
REACH	*	Contains the following SVHCs: Octamethylcyclotetrasiloxane (D4), Decamethylcyclopentasiloxane (D5), Dodecamethylcyclohexasiloxane (D6)	4/4/2022
RoHS	Y		7/2/2020
Canada Substance Grouping Initiative	Y		4/26/2012
Conflict Minerals	Y		9/12/2013
TSCA Section 6(h) - PBT Chemicals	Y		4/29/2021

* compliance is conditional based upon the amount of material imported into the EU, per the annual limit of SVHCs

Substances of Concern	Absent	Note	Date
1,1-dichloroethane	Y	Not used in the manufacturing process or formulation of raw materials	3/30/2017
1,1,1-trichloroethane	Y	Not used in the manufacturing process or formulation of raw materials	3/30/2017
1,2,4-Trichlorobenzene	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
2,4-Dichlorobenzoic Acid and its isomers	Y	Not used in the manufacturing process or formulation of raw materials	9/15/2021
2-Mercaptobenzothiazole (MBT)	Y	Not used in the manufacturing process or formulation of raw materials	4/5/2013
Aflatoxin-like compounds	Y	Not used in the manufacturing process or formulation of raw materials	4/5/2013
Aldehydes	Y	Not used in the manufacturing process or formulation of raw materials	4/5/2013
Alkanes, C10-C13, chloro	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Animal content	Y	Not used in the manufacturing process or formulation of raw materials	5/21/2012
Antibiotics	Y	Not used in the manufacturing process or formulation of raw materials	2/16/2021
Anti-microbial additives (including OBPA and DMF)	Y	Not used in the manufacturing process or formulation of raw materials	9/16/2013
Antimony Compounds	Y	Not used in the manufacturing process or formulation of raw materials	9/16/2013
Antioxidants	Y	Not used in the manufacturing process or formulation of raw materials	9/9/2015
Arsenic	Y	Not used in the manufacturing process or formulation of raw materials	9/16/2013
Asbestos	Y	Not used in the manufacturing process or formulation of raw materials	9/16/2013
Azoxy compounds	Y	Not used in the manufacturing process or formulation of raw materials	4/5/2013
BADGE (Bisphenol A diglycidyl ether)	Y	Not used in the manufacturing process or formulation of raw materials	8/25/2015
Barium	Y	Not used in the manufacturing process or formulation of raw materials	9/16/2013
Benzenamine, N-phenyl-, reaction products with styrene and 2,4,4-trimethylpentene (BNST)	Y	Not used in the manufacturing process or formulation of raw materials	3/24/2016
Benzene	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Benzoapyrene	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Benzoic Acid and Benzoates	Y	Not used in the manufacturing process or formulation of raw materials	5/6/2021
Benzophenone	Y	Not used in the manufacturing process or formulation of raw materials	2/26/2016
Benothiazole Disulfate (MBT)	Y	Not used in the manufacturing process or formulation of raw materials	3/5/2015
Beryllium and Beryllium Compounds	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Biocides	Y	Not used in the manufacturing process or formulation of raw materials	2/11/2017
Bis-DMA	Y	Not used in the manufacturing process or formulation of raw materials	8/25/2015
Bis-GMA	Y	Not used in the manufacturing process or formulation of raw materials	8/25/2015
BPA (BisPhenol A)	Y	Not used in the manufacturing process or formulation of raw materials	5/11/2012
Butyl-4-Hydroxybenzoate	Y	Not used in the manufacturing process or formulation of raw materials	11/19/2020
Carbon Tetrachloride	Y	Not used in the manufacturing process or formulation of raw materials	3/30/2017
Cellulose	Y	Not used in the manufacturing process or formulation of raw materials	5/11/2022
Cobalt	Y	Not used in the manufacturing process or formulation of raw materials	3/28/2022
Colophonium (rosin)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/2014
Colorants and Pigments	Y	Not used in the manufacturing process or formulation of raw materials	9/15/2014
Dibutyltin	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Dimethyl Fumarate	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Diocetyltn	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Dioxin	Y	Not used in the manufacturing process or formulation of raw materials	5/29/2014
Dnase (deoxyribonuclease)	Y	Not used in the manufacturing process or formulation of raw materials	8/12/2020
Epoxy Derivatives	Y	Not used in the manufacturing process or formulation of raw materials	1/6/2016
Ethoxylated BisPhenol A Diacrylate	Y	Not used in the manufacturing process or formulation of raw materials	8/25/2015
Ethyl Alcohol (potable)	Y	Not used in the manufacturing process or formulation of raw materials	12/30/2014
Fiberglass	Y	Not used in the manufacturing process or formulation of raw materials	9/16/2013
Flame retardants - Brominated (including PBB, PBDE, HBCDD, TBBPA)	Y	Not used in the manufacturing process or formulation of raw materials	9/16/2013
Flame Retardants - Non Brominated	Y	Not used in the manufacturing process or formulation of raw materials	9/16/2013
Foam Blowing Agents	Y	Not used in the manufacturing process or formulation of raw materials	9/16/2013
Food Additives (substances to preserve, add flavor, color, or texture)	Y	Not used in the manufacturing process or formulation of raw materials	8/11/2015
Food Allergens	Y	Not used in the manufacturing process or formulation of raw materials	1/6/2016
Formaldehyde	Y	Not used in the manufacturing process or formulation of raw materials	3/24/2016
Galactose	Y	Not used in the manufacturing process or formulation of raw materials	5/6/2021

Genetically Modified Organisms (GMOs)	Y	Not used in the manufacturing process or formulation of raw materials	7/10/2014
Gluten	Y	Not used in the manufacturing process or formulation of raw materials	1/5/2015
Human Blood Derivatives	Y	Not used in the manufacturing process or formulation of raw materials	3/7/2013
Inulin	Y	Not used in the manufacturing process or formulation of raw materials	3/3/2014
Iodine	Y	Not used in the manufacturing process or formulation of raw materials	5/6/2021
Irgafos antioxidant stabilizers (organo-phosphite stabilizers)	Y	Not used in the manufacturing process or formulation of raw materials	2/26/2016
Iso cyanates	Y	Not used in the manufacturing process or formulation of raw materials	4/5/2013
Isoprene	Y	Not used in the manufacturing process or formulation of raw materials	3/19/2018
Lactose	Y	Not used in the manufacturing process or formulation of raw materials	1/5/2015
Latex	Y	Not used in the manufacturing process or formulation of raw materials	4/5/2013
Magnesium Phosphate	Y	Not used in the manufacturing process or formulation of raw materials	2/12/2015
Melamine	Y	Not used in the manufacturing process or formulation of raw materials	9/14/2012
Mercury	Y	Not used in the manufacturing process or formulation of raw materials	8/27/2012
Mica	Y	Not used in the manufacturing process or formulation of raw materials	3/28/2022
Monomethyl dibromodiphenyl methane	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Monomethyl dichlorodiphenyl methane	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Monomethyl tetrachlorodiphenyl methane	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Nanomaterials - Defined as having one or more dimensions between 1 and 100 nanometers	Y	Not used in the manufacturing process or formulation of raw materials	9/16/2013
Nickel and nickel alloys	Y	Not used in the manufacturing process or formulation of raw materials	1/3/2020
Nitrates	Y	Not used in the manufacturing process or formulation of raw materials	8/11/2015
Nitrites	Y	Not used in the manufacturing process or formulation of raw materials	1/20/2020
N-Nitroso compounds (nitrosamines and nitrosamides)	Y	Not used in the manufacturing process or formulation of raw materials	4/5/2013
Nonylphenol and nonylphenol ethoxylates	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Organic Phosphates	Y	Not used in the manufacturing process or formulation of raw materials	4/5/2013
Organic Phosphites	Y	Not used in the manufacturing process or formulation of raw materials	1/12/2021
Ozone Depleting Substances	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
PCBs	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Pentachlorophenol	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Perfluorinated Carboxylic Acids or their respective salts	Y	Not used in the manufacturing process or formulation of raw materials	1/5/2015
Perfluorooctanoic acid (PFOA), and salts and esters of PFOA	Y	Not used in the manufacturing process or formulation of raw materials	3/24/2016
Perfluorooctanesulfonic Acid (PFOS)	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Persistent Organic Pollutants			10/28/2021
Pesticides	Y	Not used in the manufacturing process or formulation of raw materials	3/1/2019
Phenols	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Phenylalanine	Y	Not used in the manufacturing process or formulation of raw materials	5/6/2002
Phthalates	Y	Not used in the manufacturing process or formulation of raw materials	6/18/2012
Plant Products, including Jatropha derivatives	Y	Not used in the manufacturing process or formulation of raw materials	12/24/2014
Plasticizers in Polymers - Non Phthalate Based	Y	Not used in the manufacturing process or formulation of raw materials	9/16/2013
Plasticizers in Polymers - Phthalate Based (including DOP, DEHP, DBP, BBP, DIDP, DINP, DnOP)	Y	Not used in the manufacturing process or formulation of raw materials	9/16/2013
Polycarbonate	Y	Not used in the manufacturing process or formulation of raw materials	8/25/2015
Polycarbonate/Siloxane Copolymer	Y	Not used in the manufacturing process or formulation of raw materials	8/25/2015
Polycyclic Aromatic Hydrocarbons	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Polyaromatic hydrocarbons (PAHs)	Y	Not used in the manufacturing process or formulation of raw materials	4/5/2013
Polychlorinated and Polybrominated dioxins and furans	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Polychlorinated terphenyls	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Polychloronaphthalenes	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Polyester	Y	Not used in the manufacturing process or formulation of raw materials	5/11/2022
Polyether Sulfone	Y	Not used in the manufacturing process or formulation of raw materials	8/25/2015
Polynuclear aromatic Hydrocarbons (PNA)	Y	Not used in the manufacturing process or formulation of raw materials	3/5/2015
Polystyrene	Y	Not used in the manufacturing process or formulation of raw materials	9/24/2014
Polyurethanes, Biostable	Y	Not used in the manufacturing process or formulation of raw materials	8/25/2015
Potassium salts, including potassium bicarbonate and potassium chloride	Y	Not used in the manufacturing process or formulation of raw materials	5/6/2021
Preservatives	Y	Not used in the manufacturing process or formulation of raw materials	9/9/2015
Protease	Y	Not used in the manufacturing process or formulation of raw materials	8/12/2020
PVC - Polyvinyl Chloride - Rigid or Flexible	Y	Not used in the manufacturing process or formulation of raw materials	9/16/2013
Radioactive isotopes	Y	Not used in the manufacturing process or formulation of raw materials	9/16/2013
Refrigerants	Y	Not used in the manufacturing process or formulation of raw materials	9/16/2013
Residual monomer content in polymers intended for food, ice, water or dermal contact including Acrylonitrile, Butadiene, BisPhenol-A, Formaldehyde, Styrene, and dermal contact (including Vinyl Chloride)	Y	Not used in the manufacturing process or formulation of raw materials	9/16/2013
Residual Solvents	Y	Not used in the manufacturing process or formulation of raw materials	2/10/2017
RNase (Ribonuclease)	Y	Not used in the manufacturing process or formulation of raw materials	8/12/2020
Selenium	Y	Not used in the manufacturing process or formulation of raw materials	9/16/2013
Short-Chain Chlorinated Paraffins (SCCP's)	Y	Not used in the manufacturing process or formulation of raw materials	9/16/2013
Slip Agents (e.g. amides and/or hydrocarbons)	Y	Not used in the manufacturing process or formulation of raw materials	2/26/2016
Sodium Salts, including sodium bicarbonate and sodium chloride	Y	Not used in the manufacturing process or formulation of raw materials	5/6/2021
Sorbates, including potassium sorbate and sorbic acid	Y	Not used in the manufacturing process or formulation of raw materials	5/6/2021
Styrene	Y	Not used in the manufacturing process or formulation of raw materials	3/19/2018
Sulfur and Sulfur-containing compounds	Y	Not used in the manufacturing process or formulation of raw materials	5/31/2017
Tar Oils and Creosotes	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Tri (2,3-dibromo-propyl) phosphate	Y	Not used in the manufacturing process or formulation of raw materials	3/24/2016
Tri-2-ethylhexyl trimellitate (TEHTM)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/2014
Triclosan	Y	Not used in the manufacturing process or formulation of raw materials	9/24/2014
Trioctyl trimellitate (TOTM)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/2014
Tris (aziridinyl) phosphin oxide	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014
Tri-substituted organostannic compounds	Y	Not used in the manufacturing process or formulation of raw materials	8/7/2014

Regulations	Available	Note
NSF LISTING	Y	51
USP Class VI Compliant Ingredients	Y	
FDA Approved Ingredients	Y	CFR 177.2600



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