



145 James Way, Southampton, PA 18966
215-526-2300 • Fax: 215-526-2191
info@newageindustries.com • www.newageindustries.com

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)	7/27/21
RoHS	Y		7/2/20
Canada Substance Grouping Initiative	Y		4/26/12
Conflict Minerals	Y		9/12/13
TSCA Section 6(h) - PBT Chemicals	Y		4/29/21

* 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	3/30/17
1,1,1-trichloroethane	Y	Not used in the manufacturing process or formulation of raw materials	3/30/17
1,2,4-Trichlorobenzene	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
2,4-Dichlorobenzoic Acid and its isomers	Y	Not used in the manufacturing process or formulation of raw materials	9/15/21
2-Mercaptobenzothiazole (MBT)	Y	Not used in the manufacturing process or formulation of raw materials	4/5/13
Aflatoxin-like compounds	Y	Not used in the manufacturing process or formulation of raw materials	4/5/13
Aldehydes	Y	Not used in the manufacturing process or formulation of raw materials	4/5/13
Alkanes, C10-C13, chloro	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Animal content	Y	Not used in the manufacturing process or formulation of raw materials	5/21/12
Antibiotics	Y	Not used in the manufacturing process or formulation of raw materials	2/16/21
Anti-microbial additives (including OBPA and DMF)	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Antimony Compounds	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Antioxidants	Y	Not used in the manufacturing process or formulation of raw materials	9/9/15
Arsenic	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Asbestos	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Azoxy compounds	Y	Not used in the manufacturing process or formulation of raw materials	4/5/13
BADGE (Bisphenol A diglycidyl ether)	Y	Not used in the manufacturing process or formulation of raw materials	8/25/15
Barium	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
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	3/24/16
Benzene	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Benzoapyrene	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Benzoic Acid and Benzoates	Y	Not used in the manufacturing process or formulation of raw materials	5/6/21
Benzophenone	Y	Not used in the manufacturing process or formulation of raw materials	2/26/16
Benzothiazole Disulfate (MBT)	Y	Not used in the manufacturing process or formulation of raw materials	3/5/15
Beryllium and Beryllium Compounds	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Biocides	Y	Not used in the manufacturing process or formulation of raw materials	2/11/17
Bis-DMA	Y	Not used in the manufacturing process or formulation of raw materials	8/25/15
Bis-GMA	Y	Not used in the manufacturing process or formulation of raw materials	8/25/15
BPA (BisPhenol A)	Y	Not used in the manufacturing process or formulation of raw materials	5/11/12
Butyl-4-Hydroxybenzoate	Y	Not used in the manufacturing process or formulation of raw materials	11/19/20
Carbon Tetrachloride	Y	Not used in the manufacturing process or formulation of raw materials	3/30/17
Colophonium (rosin)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/14
Colorants and Pigments	Y	Not used in the manufacturing process or formulation of raw materials	9/15/14
Dibutyltin	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Dimethyl Fumarate	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Diocetyl tin	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Dioxin	Y	Not used in the manufacturing process or formulation of raw materials	5/29/14
Dnase (deoxyribonuclease)	Y	Not used in the manufacturing process or formulation of raw materials	8/12/20
Epoxy Derivatives	Y	Not used in the manufacturing process or formulation of raw materials	1/6/16
Ethoxylated BisPhenol A Diacrylate	Y	Not used in the manufacturing process or formulation of raw materials	8/25/15
Ethyl Alcohol (potable)	Y	Not used in the manufacturing process or formulation of raw materials	12/30/14
Fiberglass	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Flame retardants - Brominated (including PBB, PBDE, HBCDD, TBBPA)	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Flame Retardants - Non Brominated	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Foam Blowing Agents	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Food Additives (substances to preserve, add flavor, color, or texture)	Y	Not used in the manufacturing process or formulation of raw materials	8/11/15
Food Allergens	Y	Not used in the manufacturing process or formulation of raw materials	1/6/16
Formaldehyde	Y	Not used in the manufacturing process or formulation of raw materials	3/24/16
Galactose	Y	Not used in the manufacturing process or formulation of raw materials	5/6/21
Genetically Modified Organisms (GMOs)	Y	Not used in the manufacturing process or formulation of raw materials	7/10/14
Gluten	Y	Not used in the manufacturing process or formulation of raw materials	1/5/15
Human Blood Derivatives	Y	Not used in the manufacturing process or formulation of raw materials	3/7/13
Inulin	Y	Not used in the manufacturing process or formulation of raw materials	3/3/14
Iodine	Y	Not used in the manufacturing process or formulation of raw materials	5/6/21
Irgafos antioxidant stabilizers (organo-phosphite stabilizers)	Y	Not used in the manufacturing process or formulation of raw materials	2/26/16
Isocyanates	Y	Not used in the manufacturing process or formulation of raw materials	4/5/13

Isoprene	Y	Not used in the manufacturing process or formulation of raw materials	3/19/18
Lactose	Y	Not used in the manufacturing process or formulation of raw materials	1/5/15
Latex	Y	Not used in the manufacturing process or formulation of raw materials	4/5/13
Magnesium Phosphate	Y	Not used in the manufacturing process or formulation of raw materials	2/12/15
Melamine	Y	Not used in the manufacturing process or formulation of raw materials	9/14/12
Mercury	Y	Not used in the manufacturing process or formulation of raw materials	8/27/12
Monomethyl dibromodiphenyl methane	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Monomethyl dichlorodiphenyl methane	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Monomethyl tetrachlorodiphenyl methane	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
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	9/16/13
Nickel and nickel alloys	Y	Not used in the manufacturing process or formulation of raw materials	1/3/20
Nitrates	Y	Not used in the manufacturing process or formulation of raw materials	8/11/15
Nitrites	Y	Not used in the manufacturing process or formulation of raw materials	1/20/20
N-Nitroso compounds (nitrosamines and nitrosamides)	Y	Not used in the manufacturing process or formulation of raw materials	4/5/13
Nonylphenol and nonylphenol ethoxylates	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Organic Phosphates	Y	Not used in the manufacturing process or formulation of raw materials	4/5/13
Organic Phosphites	Y	Not used in the manufacturing process or formulation of raw materials	1/12/21
Ozone Depleting Substances	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
PCBs	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Pentachlorophenol	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Perfluorinated Carboxylic Acids or their respective salts	Y	Not used in the manufacturing process or formulation of raw materials	1/5/15
Perfluorooctanoic acid (PFOA), and salts and esters of PFOA	Y	Not used in the manufacturing process or formulation of raw materials	3/24/16
Perfluorooctanesulfonic Acid (PFOS)	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Pesticides	Y	Not used in the manufacturing process or formulation of raw materials	3/1/19
Phenols	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Phenylalanine	Y	Not used in the manufacturing process or formulation of raw materials	5/6/02
Phthalates	Y	Not used in the manufacturing process or formulation of raw materials	6/18/12
Plant Products, including Jatropa derivatives	Y	Not used in the manufacturing process or formulation of raw materials	12/24/14
Plasticizers in Polymers - Non Phthalate Based	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
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	9/16/13
Polycarbonate	Y	Not used in the manufacturing process or formulation of raw materials	8/25/15
Polycarbonate/Siloxane Copolymer	Y	Not used in the manufacturing process or formulation of raw materials	8/25/15
Polycyclic Aromatic Hydrocarbons	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Polyaromatic hydrocarbons (PAHs)	Y	Not used in the manufacturing process or formulation of raw materials	4/5/13
Polychlorinated and Polybrominated dioxins and furans	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Polychlorinated terphenyls	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Polychloronaphthalenes	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Polyether Sulfone	Y	Not used in the manufacturing process or formulation of raw materials	8/25/15
Polynuclear aromatic Hydrocarbons (PNA)	Y	Not used in the manufacturing process or formulation of raw materials	3/5/15
Polystyrene	Y	Not used in the manufacturing process or formulation of raw materials	9/24/14
Polyurethanes, Biostable	Y	Not used in the manufacturing process or formulation of raw materials	8/25/15
Potassium salts, including potassium bicarbonate and potassium chloride	Y	Not used in the manufacturing process or formulation of raw materials	5/6/21
Preservatives	Y	Not used in the manufacturing process or formulation of raw materials	9/9/15
Protease	Y	Not used in the manufacturing process or formulation of raw materials	8/12/20
PVC - Polyvinyl Chloride - Rigid or Flexible	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Radioactive isotopes	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Refrigerants	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
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	9/16/13
Residual Solvents	Y	Not used in the manufacturing process or formulation of raw materials	2/10/17
RNase (Ribonuclease)	Y	Not used in the manufacturing process or formulation of raw materials	8/12/20
Selenium	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Short-Chain Chlorinated Paraffins (SCCP's)	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Slip Agents (e.g. amides and/or hydrocarbons)	Y	Not used in the manufacturing process or formulation of raw materials	2/26/16
Sodium Salts, including sodium bicarbonate and sodium chloride	Y	Not used in the manufacturing process or formulation of raw materials	5/6/21
Sorbates, including potassium sorbate and sorbic acid	Y	Not used in the manufacturing process or formulation of raw materials	5/6/21
Styrene	Y	Not used in the manufacturing process or formulation of raw materials	3/19/18
Sulfur and Sulfur-containing compounds	Y	Not used in the manufacturing process or formulation of raw materials	5/31/17
Tar Oils and Creosotes	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Tri (2,3-dibromo-propyl) phosphate	Y	Not used in the manufacturing process or formulation of raw materials	3/24/16
Tri-2-ethylhexyl trimellitate (TEHTM)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/14
Triclosan	Y	Not used in the manufacturing process or formulation of raw materials	9/24/14
Trioctyl trimellitate (TOTM)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/14
Tris (aziridinyl) phosphin oxide	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Tri-substituted organostannic compounds	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Regulations	Available	Note	
USP Class VI Compliant Ingredients	Y		
FDA Approved Ingredients	Y	CFR 177.2600	

Sonja McClennen

Sonja McClennen - Regulatory Compliance Manager
NewAge Industries/AdvantaPure
productmanagement@newageindustries.com