

## MATERIAL AND REGULATORY INFORMATION SUMMARY

### APSH, APSH-DB - Platinum Cured Silicone; Inner Liner (NI202); Shore 70A - Product Series A710, A714

Legislation	Compliant	Note	Date
REACH	*	Contains the following SVHCs: Octamethylcyclotetrasiloxane (D4), Decamethylcyclopentasiloxane (D5), Dodecamethylcyclohexasiloxane (D6)	7/27/21
RoHS	Y		5/30/18
Canada Substance Grouping Initiative	Y		4/26/12
Conflict Minerals	Y		9/10/13
TSCA Section 6(h) PBT Chemicals	Y		9/22/21

\* 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-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, C10-13, chloro	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Animal content	Y	Not used in the manufacturing process or formulation of raw materials	3/7/13
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	7/14/14
Aromatic Substances	Y	Not used in the manufacturing process or formulation of raw materials	10/15/19
Arsenic	Y	Not used in the manufacturing process or formulation of raw materials	7/16/13
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
Benzalkonium Chloride	Y	Not used in the manufacturing process or formulation of raw materials	1/7/19
Benzene	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Benzoapryene	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	1/7/19
Benzophenone	Y	Not used in the manufacturing process or formulation of raw materials	2/26/16
Benzyl Alcohol	Y	Not used in the manufacturing process or formulation of raw materials	1/7/19
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	4/11/17
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
BNST (Benzenamine, N-phenyl-, Reaction Products with Styrene and 2,4,4-Trimethylpentene)	Y	Not used in the manufacturing process or formulation of raw materials	3/24/16
Boric Acid and Borates	Y	Not used in the manufacturing process or formulation of raw materials	1/7/19
BPA (BisPhenol A)	Y	Not used in the manufacturing process or formulation of raw materials	10/6/08
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
Colorants and Pigments	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Cyclodextrins	Y	Not used in the manufacturing process or formulation of raw materials	1/7/19
Dextrans	Y	Not used in the manufacturing process or formulation of raw materials	1/7/19
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	7/14/14
Emulsifiers	Y	Not used in the manufacturing process or formulation of raw materials	9/21/21
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
Flavors	Y	Not used in the manufacturing process or formulation of raw materials	9/15/14
Foam blowing agents	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Food Additives	Y	Not used in the manufacturing process or formulation of raw materials	8/11/15
Food Allergens (major), including Gluten and Lactose	Y	Not used in the manufacturing process or formulation of raw materials	1/5/15
Formaldehyde	Y	Not used in the manufacturing process or formulation of raw materials	3/24/16
Fragrance Allergens	Y	Not used in the manufacturing process or formulation of raw materials	1/7/19
Fructose	Y	Not used in the manufacturing process or formulation of raw materials	1/7/19
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	3/7/13
Glutamates	Y	Not used in the manufacturing process or formulation of raw materials	9/15/14
Heavy Metals	Y	Not used in the manufacturing process or formulation of raw materials	2/9/15
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
Jatropha Plant Derivatives	Y	Not used in the manufacturing process or formulation of raw materials	8/16/12
Latex	Y	Not used in the manufacturing process or formulation of raw materials	9/15/14
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	3/15/12
Mercury	Y	Not used in the manufacturing process or formulation of raw materials	8/8/12
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
Natural Rubber	Y	Not used in the manufacturing process or formulation of raw materials	9/15/14
Nanomaterials	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
Organo-phosphite stabilizers (e.g. Irgafos®)	Y	Not used in the manufacturing process or formulation of raw materials	2/26/16
Ozone Depleting Substances	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 (Aspartame)	Y	Not used in the manufacturing process or formulation of raw materials	9/15/14
Phosphates	Y	Not used in the manufacturing process or formulation of raw materials	1/7/19
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
Polyaromatic hydrocarbons (PAHs)	Y	Not used in the manufacturing process or formulation of raw materials	4/1/13
Polycarbonate	Y	Not used in the manufacturing process or formulation of raw materials	8/25/15
Polychlorinated and Polybrominated dioxins and furans	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Polychlorinated biphenyls (PCBs)	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
Polysorbates	Y	Not used in the manufacturing process or formulation of raw materials	1/7/19
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	7/14/14
Proline	Y	Not used in the manufacturing process or formulation of raw materials	1/7/19
Propylene Glycol and esters	Y	Not used in the manufacturing process or formulation of raw materials	1/7/19
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 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	2/9/15
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, hydrocarbons)	Y	Not used in the manufacturing process or formulation of raw materials	2/26/16
Sodium	Y	Not used in the manufacturing process or formulation of raw materials	1/7/19
Sodium Lauryl Sulfate	Y	Not used in the manufacturing process or formulation of raw materials	1/7/19
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
Sorbitol	Y	Not used in the manufacturing process or formulation of raw materials	1/7/19
Stabilizers	Y	Not used in the manufacturing process or formulation of raw materials	10/15/19
Styrene	Y	Not used in the manufacturing process or formulation of raw materials	3/19/18
Sulfites	Y	Not used in the manufacturing process or formulation of raw materials	9/15/14
Sulfur and Sulfur-containing compounds	Y	Not used in the manufacturing process or formulation of raw materials	5/31/17
Synthetic Colors	Y	Not used in the manufacturing process or formulation of raw materials	9/15/14
Talc	Y	Not used in the manufacturing process or formulation of raw materials	9/21/21
Tar Oils and Creosotes	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Thickeners	Y	Not used in the manufacturing process or formulation of raw materials	9/21/21
Tri(2,3-dibromo-propyl) phosphate	Y	Not used in the manufacturing process or formulation of raw materials	3/24/16
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 Testing	Y	85; 87; 88 (Class VI) 70 C for 24 Hrs; 381; 661
ISO Testing	Y	10993
NSF LISTING	Y	51
3-A Sanitary Procedure	Y	18-3 Class I
FDA Testing	Y	21 CFR 177.2600
European Pharmacopeia Testing	Y	3.1.9



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