

## MATERIAL AND REGULATORY INFORMATION SUMMARY

### Ultra Low Temperature LIM - Liquid Injection Molding Material (NI 212); Shore 69A - Product Series A131

Legislation	Compliant	Note	Date
REACH	*	Contains the following SVHCs: Octamethylcyclotetrasiloxane (D4), Decamethylcyclopentasiloxane (D5), Dodecamethylcyclohexasiloxane (D6)	7/27/21
RoHS	Y		9/6/18
Conflict Minerals	Y		8/29/18

\* 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
1,2,4-Trichlorobenzene	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
2-Mercaptobenzothiazole (MBT)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Aflatoxin-like compounds	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Aldehydes	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Alkanes, C10-C13, chloro	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Animal content	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Anti-microbial additives (including OBPA and DMF)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Antimony Compounds	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Arsenic	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Asbestos	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Azoxy compounds	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
BADGE (Bisphenol A diglycidyl ether)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Barium	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
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	9/24/18
Benzene	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Benzoapyrene	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Benzophenone	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Benzothiazole Disulfate (MBT)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Beryllium and Beryllium Compounds	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Bis-DMA	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Bis-GMA	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
BPA (BisPhenol A)	Y	Not used in the manufacturing process or formulation of raw materials	8/29/18
Colophonium (rosin)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Colorants and Pigments	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Dibutyltin	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Dimethyl Fumarate	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Diocetyl tin	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Dioxin	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Epoxy Derivatives	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Ethoxylated BisPhenol A Diacrylate	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Ethyl Alcohol (potable)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Fiberglass	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Flame retardants - Brominated (including PBB, PBDE, HBCDD, TBBPA)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Flame Retardants - Non Brominated	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Foam Blowing Agents	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Food Additives (substances to preserve, add flavor, color, or texture)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Food Allergens	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Formaldehyde	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Genetically Modified Organisms (GMOs)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Gluten	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Human Blood Derivatives	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Inulin	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Irgafos antioxidant stabilizers (organo-phosphite stabilizers)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Isocyanates	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Jatropha Plant Derivatives	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Lactose	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Latex	Y	Not used in the manufacturing process or formulation of raw materials	8/29/18
Magnesium Phosphate	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Melamine	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Mercury	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Monomethyl dibromodiphenyl methane	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Monomethyl dichlorodiphenyl methane	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Monomethyl tetrachlorodiphenyl methane	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
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	9/24/18
Nickel and nickel alloys	N	Used in the manufacturing/molding process	12/19/18
Nitrates	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
N-Nitroso compounds	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Nonylphenol and nonylphenol ethoxylates	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18

Organic Phosphates	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Ozone Depleting Substances	Y	Not used in the manufacturing process or formulation of raw materials	8/29/18
PCBs	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Pentachlorophenol	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Perfluorinated Carboxylic Acids or their respective salts	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Perfluorooctanoic acid (PFOA), and salts and esters of PFOA	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Perfluorooctanesulfonic Acid (PFOS)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Phenols	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Phthalates	Y	Not used in the manufacturing process or formulation of raw materials	8/29/18
Plasticizers in Polymers - Non Phthalate Based	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
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	9/24/18
Polycarbonate	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Polycarbonate/Siloxane Copolymer	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Polycyclic Aromatic Hydrocarbons	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Polyaromatic hydrocarbons (PAHs)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Polychlorinated and Polybrominated dioxins and furans	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Polychlorinated terphenyls	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Polychloronaphthalenes	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Polyether Sulfone	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Polynuclear aromatic Hydrocarbons (PNA)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Polystyrene	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Polyurethanes, Biostable	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
PVC - Polyvinyl Chloride - Rigid or Flexible	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Radioactive isotopes	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Refrigerants	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
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	9/24/18
Selenium	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Short-Chain Chlorinated Paraffins (SCCP's)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Slip Agents (e.g. amides and/or hydrocarbons)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Sulfur Hexafluoride	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Tar Oils and Creosotes	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Tri (2,3-dibromo-propyl) phosphate	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Tri-2-ethylhexyl trimellitate (TEHTM)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Triclosan	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Trioctyl trimellitate (TOTM)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Tris (aziridinyl) phosphin oxide	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18
Tri-substituted organostannic compounds	Y	Not used in the manufacturing process or formulation of raw materials	9/24/18

Regulations	Available	Note
USP Testing	Y	85; 87; 88 (Class VI) 70 C for 24 Hrs; 381; 643; 661; 788
ISO Testing	Y	10993
FDA Testing	Y	CFR 177.2600
European Pharmacopeia Testing	Y	EP 3.1.9; 3.2.9
Japanese Pharmacopeia Testing	Y	JP 7.03



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