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MATERIAL AND REGULATORY INFORMATION SUMMARY

Silbrade® Medical - Medical Grade Braid Reinforced Silicone Hose - Product Series 291

Legislation	Compliant	Note	Date
REACH	*	Contains the following SVHC: Octamethylcyclotetrasiloxane (D4)	4/4/2022
RoHS	Y		7/24/2015
Conflict Minerals	Y		3/21/2013
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
Animal content	Y	Not used in the manufacturing process or formulation of raw materials	3/26/2014
Anti-microbial additives (including OBPA and DMF)	Y	Not used in the manufacturing process or formulation of raw materials	5/16/2014
Antimony Compounds	Y	Not used in the manufacturing process or formulation of raw materials	5/16/2014
Arsenic	Y	Not used in the manufacturing process or formulation of raw materials	5/16/2014
Asbestos	Y	Not used in the manufacturing process or formulation of raw materials	5/16/2014
Barium	Y	Not used in the manufacturing process or formulation of raw materials	5/16/2014
BisPhenol A (BPA)	Y	Not used in the manufacturing process or formulation of raw materials	5/15/2014
Colorants and Pigments	Y	Not used in the manufacturing process or formulation of raw materials	5/16/2014
Fiberglass	Y	Not used in the manufacturing process or formulation of raw materials	5/16/2014
Flame retardants - Brominated (including PBB, PBDE, HBCDD, TBBPA)	Y	Not used in the manufacturing process or formulation of raw materials	5/16/2014
Flame Retardants - Non Brominated	Y	Not used in the manufacturing process or formulation of raw materials	5/16/2014
Foam Blowing Agents	Y	Not used in the manufacturing process or formulation of raw materials	5/16/2014
Latex	Y	Not used in the manufacturing process or formulation of raw materials	9/9/2015
Mercury	Y	Not used in the manufacturing process or formulation of raw materials	7/24/2015
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	5/16/2014
Nitrosamines	Y	Not used in the manufacturing process or formulation of raw materials	8/3/2020
Plasticizers in Polymers - Non-Phthalate Based	Y	Not used in the manufacturing process or formulation of raw materials	5/16/2014
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	5/16/2014
PVC - Polyvinyl Chloride - Rigid or Flexible	Y	Not used in the manufacturing process or formulation of raw materials	5/16/2014
Radioactive isotopes	Y	Not used in the manufacturing process or formulation of raw materials	5/16/2014
Refrigerants	Y	Not used in the manufacturing process or formulation of raw materials	5/16/2014
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	5/16/2014
Selenium	Y	Not used in the manufacturing process or formulation of raw materials	5/16/2014
Short-Chain Chlorinated Paraffins	Y	Not used in the manufacturing process or formulation of raw materials	5/16/2014
Triclosan	Y	Not used in the manufacturing process or formulation of raw materials	5/21/2013

Regulations	Available	Note
USP Testing	Y	88 (Class VI)
FDA Approved Ingredients	Y	21 CFR 177.2600

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