

May 1, 2025

Re: Compliance and Processing Information for SaniSure Stir Bar Products

Materials of Construction

There are two material types of SaniSure Stir Bar products. One stir bar is manufactured from PVDF and the other stir bar product is manufactured from polypropylene. The following are the details of each stir bar raw material:

- The PVDF stir bar products are manufactured from Kynar 720 or Kynar 740 resin and a neodymium magnet, material is NdFEB, grade N42.
- The polypropylene stir bar products are manufactured from Propylux HS2 resin and a neodymium magnet, material is NdFEB, grade N42.

Country of Origin

All raw materials used in these stir bar products are sourced from United States based companies. All processing operations are performed in the United States as well.

Biocompatibility

The PVDF material meets FDA, Class VI (USP <88>), ISO 10993-4 (Hemolysis), and ISO 10993-5 (In Vitro Cytotoxicity) requirements.

This polypropylene material meets FDA, Class VI (USP <88>) requirements, and meets ISO 10993-5 (In Vitro Cytotoxicity) requirements.

Statement Regarding Storage Conditions and Shelf Life (Sterile and Non-Sterile)

The shelf life of SaniSure products is dependent upon the storage conditions. In general, it is best to store these products in a cool dry environment (ambient temperature, 15-30°C) shielded from direct sunlight. It is best to store in the original packaging until ready to use.

These stir bar products that are packaged at the SaniSure facility and gamma irradiated are given a shelf life of two years and assurance of sterility within this shelf life period.

The shelf life of non-gamma irradiated stir bar products:

- PVDF stir bar products shelf life is indefinite as the degradation of the Kynar PVDF material stored over a long period of time is negligible.
- Polypropylene stir bars can be stored for up to 10 years.

Animal Derivative Content & Transmissible Spongiform Encephalitis (BSE/TSE) Risk

Based on information provided by our suppliers, the p material used in these products is free of substances which are animal derived or associated with BSE/TSE infectivity.

Conflict Minerals

Conflict minerals are not used in the formulation of the raw material or stir bar products.

Bisphenol A (BPA) and Phthalates

BPA and Phthalates are not used in the formulation of the raw material or manufacture of these SaniSure stir bar products.

Latex

Based on information provided by our suppliers, the component materials used in SaniSure stir bar products are free from Latex and also not used in the assembly manufacturing process.

Melamine

Melamine is not used in the formulation of the raw material or manufacture of these SaniSure stir bar products.

Genetically Modified Organisms (GMO)

The component materials used in the manufacture of these stir bar products are synthetic in nature and produced by chemical synthesis. Genetically Modified Organisms are not used in the manufacturing or processing of any of the materials used in these products that come in contact with the fluid pathway.

Restriction of Hazardous Substances (RoHS) - EU

Based on a review of the final product composition by the resin manufacturer, there are no RoHS substances known to be present above the reporting threshold.

REACH SVHC

Based on a review of the final product composition by the resin manufacturer, this product is not a Substance of Very High Concern and does not contain any SVHC substance(s) above the declaration threshold.

Sincerely,



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