



The Best Home a Drug Can Get™

Effective Date: March 23, 2023

Expiration Date: Earlier of one year of change to law(s) cited below.

Re: PVDF Tubing Regulatory Information

Allergens

Based on the information made available to SANISURE by its material supplier, the above products do not contain any common allergens including:

- Bee and bee products
- Certain Foods: Celery, Tomato, Yam, Apple, Orange, Peach,
- Kiwi, Banana, Mushroom, Chicken, Beef, Pork
- Coconut and coconut derivatives
- Crustacean shellfish, mollusks, fish and fish products
- Egg and egg products
- Gelatin
- Milk and Milk Products
- Mustard, Lupine, sesame and their derivatives
- Other Gluten Containing Cereals
- Peanut and unrefined peanut derivatives
- Soy and unrefined soy derivatives
- Soy derived highly refined substances
- Sulfites > 10 ppm
- Tree nuts and unrefined tree nut derivatives
- Wheat, Wheat Varieties, and their Derivatives

Animal Derivatives (BSE/ TSE)

Based on the information provided to SANISURE by its raw material suppliers and review of our product formula and our materials handling and processing procedures, we have been able to determine that the product listed above does not contain ingredients derived from animals including animal fats (tallow).

Based on this information there would be no known sources of Bovine Spongiform Encephalopathy (BSE) or Transmissible spongiform encephalopathy (TSE).

Regulatory Compliances

Based on the information made available to us by our raw material supplier, the above material is compliant to the below list of regulatory requirements.

- RoHs 3 Directive 2015/863 Compliant
- REACH Compliant (233 SVHC)
- Conflict Minerals
- California Proposition 65

Substances

Based on the information made available to us by our raw material supplier, we have found that the product listed above does not intentionally contain the following substances:

- Bisphenol A (BPA)
- Latex
- Melamine
- Nitrosamines
- Phthalates (plasticizers)
- Per- and Polyfluoroalkyl substances (PFAS)
- PVC

Toxic Substances Control Act of 1976 (TSCA)

Based on the information made available to SaniSure by its material suppliers, this product meets the requirements of the TSCA.

USP Class VI, ISO 10993

Based on the information made available to SANISURE by its material supplier, the above products meet the requirements of USP Class VI.

The information submitted is valid as of the date of this letter. SANISURE makes no representations or warranties as to the accuracy of the information contained or referenced herein as of any other date. If you have any questions concerning this matter or if we can be of further assistance, please do not hesitate to contact us. Please contact your SANISURE Corporation Sales Representative should you need additional product support.

Sincerely,

David Alexander

David Alexander
SaniSure Sparta
18 White Lake Rd.
Sparta, NJ 07871
dalexander@sanisure.com