



The Best Home a Drug Can Get™

August 18, 2022

Re: PTFE Tubing Regulatory Statement

Animal Derivatives, Plant Derivatives, BSE/TSE Statement

Based on the information made available to us by our material suppliers, the above product does not contain materials of animal origin.

FDA 21CFR 177.1550

Based on the information made available to TBL by its suppliers, we have been able to determine that the product listed above conforms to FDA 21CFR 177.1550.

Presence of Substances

Based on the information made available to TBL Plastics by its material supplier, none of the following compounds are intentionally added in as a 'raw material' or as a 'process aid' to the above product:

- Bisphenol A (BPA)
- Melamine
- Natural latex rubber (NRL)
- Phthalates
- Cyanuric Acid
- N-Nitrosamines
- PVC
- Plasticizers
- Solvents

REACH

Based on the information made available to us by our material suppliers, the above products to the best of our knowledge do not contain any of the substances listed in Regulation (EC) N° 1907/2006 in a concentration above 0.1%. (224 Substances)

RoHS

Based on the information made available to us by our material suppliers substances listed within RoHS are neither used as raw materials nor intentionally added to the TBL Performance Plastics product listed above. Thus, we believe that this product meets Directive 2002/95/EC ("RoHS").

USP Class VI

Based on the information made available by our material suppliers, the above product meets the requirements of USP Class VI.

The information submitted is valid as of the date of this letter. TBL makes no representations or warranties as to the accuracy of the information contained or referenced herein as of any other date. Most results mentioned above are based on single lots of material. Although a lot-to-lot variance would not be expected to show different results, this data should not be construed as a warranty of fitness for use. Prior to use for any application, the user has the sole responsibility for determining the suitability of these products in any application. If you have any questions concerning this document or if we can be of further assistance, please do not hesitate to contact us. Please do not hesitate to contact our quality department at quality.nj@sanisure.com or 973.383.2834 for more information.

Sincerely,

David Alexander

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