

Pharma-Line I Regulatory Statement

Manufacturing Standard

The above material is manufactured in an ISO 9001:2015 accredited facility. This product is manufactured in an unclassified, controlled environment.

Dimensional Tolerances

Inside and outside diameter tolerances are maintained to RMA E1 tolerances. Overall length tolerance is maintained to +6in. (min.) / -0 in.

Regulatory Testing

- **Biocompatibility (USP 87 and USP 88)***
Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the below testing standards:
 - USP 87
 - USP 88
- **Biocompatibility (ISO 10993 and USP Class VI)***
A Representative sample of the compound used to manufacture this product has been tested according to ISO 10993 and USP Class VI testing requirements. The sample met the requirements of the following tests:
 - Systemic Injection Test (USP Class VI and ISO 10993)
 - Intracutaneous Toxicity Test (USP Class VI and ISO 10993)
 - Intramuscular Implantation Test (USP Class VI and ISO 10993)
 - Agar Diffusion (ISO 10993-5)
 - L929 MEM Elution (ISO 10993-5)
 - Hemolysis-Rabbit Blood (ISO 10993-4)
- **Extractables - USP***
Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the below testing standards:
 - USP 661.2

- **Endotoxin Testing***

Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the below testing standard:

- USP 85

- **Particulate Testing***

Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the below testing standard:

- USP 788

*The assessment is available upon request at <https://sanisure.com/get-report/>

Presence of Substances

Based on the information provided to SaniSure by its raw material suppliers, we have found that the material listed above does not intentionally contain the following substances:

- Bisphenol A (BPA)
- Latex / Natural Rubber Latex / Natural Rubber
- Melamine
- N-Nitrosamines
- Phthalates
 - According to the raw material supplier, there may be a trace residual amount of phthalate(s) from the olefin component(s) utilized in this compound, which would be an impurity left from the catalytic system.
- Polyvinyl chloride (PVC)
- Slip Agents

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 Compliant
- REACH Compliant (223 SVHC)
- Conflict Minerals
- California Proposition 65
- ICH Q3D Elemental Impurities

Animal Derivatives, Plant Derivatives, BSE/TSE Statement*

The product listed above does contain a tallow derived substance. The tallow derived raw material used in the manufacture of our product is in compliance with the Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev.3) because the processing exceeds the following condition from section 6.4 of the note: trans-esterification or hydrolysis at not less than 200 °C for not less than 20 minutes under pressure (glycerol, fatty acids and fatty acid esters production), therefore presents minimal or no risk of transmitting BSE/TSE. Please note we do not routinely test for these materials. Our information is based on data provided by our suppliers.

Genetically Modified Organisms (GMO's)

GMO's may be present in the product listed above as a result of specific characteristics of the raw materials utilized by SaniSure's supplier and/or of their manufacturing process(es).

Allergens

Based on the information provided to SaniSure by its raw material suppliers, we have found that the material listed above does not intentionally contain any known sources of the following Allergens:

- Milk
- Eggs
- Fish
- Crustacean shellfish
- tree nuts (e.g., almonds, pecans, or walnuts)
- wheat
- peanuts and soybeans
- celery
- cottonseed
- gluten including grain (i.e. cereals)
- legumes
- lupin
- mollusks
- monosodium glutamate (MSG)
- mustard
- poppy seeds
- sesame seeds
- sodium metabisulfite
- sulfites
- sulfur dioxide
- sunflower seeds.

Note: SaniSure has been notified by our raw material supplier that at least one component may contain a soybean source.

SaniSure does not intentionally add or use these substances in the manufacturing process of this product(s).

*Please note that the information provided is based on best available knowledge; we do not test for the presence of trace amounts of substances that may be introduced our products as contaminants. We do not routinely analyze our products for the presence of the above reportable substances; however, based on information provided by our supplier and to the best of our knowledge, the above material is free from animal derivatives.

Sterilization

Gamma Irradiation

The recommended maximum dosage for gamma irradiation of the above product is 50 kGy. When required of SaniSure, the standard range for gamma irradiation of products is between 25 and 40 kGy.

Shelf Life and Storage Conditions

If stored according to the following recommendations, SaniSure recommends that customers dispose of this product after seven (7) years from the date of manufacturing. Store this product in a dry inside environment with a target ambient temperature of 77°F and humidity of less than 65%. The product should be free from exposure to direct outside weather influences and stored in a dark space out of direct contact with light. The area should be free from volatile solvents, corrosive gases, or other potentially harmful vapors. Stack the product flat in an opaque container during storage. The container should be kept off the floor (e.g., on shelving or skids) and remain closed and sealed while in storage. The product should be free of kinking and not be subjected to crushing forces from the weight of the product above it.

SaniSure makes no representations or warranties as to the accuracy of the information contained or referenced herein.—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.

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