

August 1, 2022

Re: Nylon Tri-Clamp General Statement

Allergens

Allergens, such as cereals, gluten, crustacean shellfish, eggs, fish, peanuts, soybeans, milk, nuts, celery, mustard, sesame seeds, sulfur dioxide, sulfites, lupin, and mollusks are not intentionally added to this product to the best of our knowledge based on the information made available.

Animal Derivatives

Based on the information made available to us by our material supplier, additives of animal origin are not intentionally added during the manufacturing process.

Bisphenol A (BPA)

Based on the information made available to us by our material supplier, bisphenol A (BPA) is not intentionally added during the manufacturing process or expected to be contained in the above product.

Conflict Minerals

No 3TG (Tin, Tantalum, Tungsten, Gold) materials or extended minerals (Cobalt and Mica) are utilized in the resins used to make the above product, based on the information made available to us by our material suppliers.

EU Persistent Organic Pollutants (POP)

Based on the information made available to SANISURE by its raw material suppliers, the above product does not contain persistent organic pollutants. Such substances are not expected to be present in the above product.

FDA 21CFR177.1500

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 21CFR177.1500.

ISO 10993

Based on the information made available to TBL by its suppliers, we have been able to determine that the product listed above conforms meets the requirements of ISO 10993: Biological Evaluation of Medical Devices.

Melamine

Based on the information made available to us by our material supplier, Melamine is not intentionally added to the resin utilized and not expected to be present within the above product.

REACH

Based on the information made available to TBL Performance Plastics by its 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

Per Directives 2011/65/EU and (EU) 2015/863, the four identified metals, phthalates, and two flame retardant families are not present above maximum concentration as described in annex II or its amendments of the RoHS 2 directive.

Shelf Life and Storage Conditions

The recommended shelf life of the above-mentioned product is 5 years from the date of manufacturing. This applies to new and unused product utilizing the following storage conditions: Store the product in a dry inside environment with an ambient temperature below 77°F. 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.

Sterilization Conditions

The above-mentioned product is compatible with autoclaving and gamma irradiation.

US Toxic Substances Control Act (TSCA)

Based on the information made available by our material suppliers, the above product is in compliance with the US TSCA inventory.

USP Class VI

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

Sincerely,

David Alexander

David Alexander

Quality Specialist

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