

October 8, 2020

Subject: **Compliance Declaration Statements for the Mixed4Sure Pronto Cap Assembly Products**

### **Product Description**

The SaniSure Mixed4Sure Pronto product line was developed for use with four carboy sizes. They include the following carboy sizes and associated Mixed4Sure product: 5L (SS-M4S-5L), 10L (SS-M4S-10L), 20L (SS-M4S-20L), and 50L (SS-M4S-50L).

### **Manufacturing Process of the SaniSure Mixed4Sure Pronto**

The preliminary fabrication steps for Mixed4Sure Cap Assembly products are performed by an ISO 9001:2015 certified machining contractor. The final fabrication, assembly, cleaning, and packaging steps take place at SaniSure in a controlled fabrication environment and validated ISO Class 7 cleanrooms.

### **Materials of Construction**

This product contact materials of construction used to manufacture the Mixed4Sure cap assemblies meet Class VI (USP <88>) requirements.

### **Country of Origin**

All raw materials used in these Mixed4Sure products are sourced from United States based companies. All processing operations are performed in the United States.

### **Statement Regarding Storage Conditions and Shelf Life**

The shelf life of these products is dependent upon the storage conditions. In general, it is best to store these products in a cool dry environment (15 to 30 °C and humidity range of 40 to 55 % RH shielded from direct sunlight). It is best to store in the original packaging until ready to use.

We have not conducted accelerated aging or real-time shelf life testing on these non-gamma irradiated Mixed4Sure cap assembly products. Our experience for the materials used in these products shows no significant product degradation for product maintained in these storage conditions for up to five years. Therefore, the shelf life of these products is estimated to be five years from date of manufacture if the storage conditions comply with those described above.

This five-year shelf life is very conservative and storage beyond five years should be validated by the end user to ensure product integrity and functionality prior to use.

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

SaniSure continuously works to assure the safety of our products with respect to potential BSE/TSE transmission by working through our supply chain to obtain information regarding the possible use of animal-based material and to confirm specific sourcing and processing details, where applicable.

All product contact materials used in these products are animal derived component free or compliant with EMEA/410/01 Rev. 3.

**Allergens**

The materials used to manufacture these products do not contain allergens as defined by the FDA (Milk, Eggs, Fish, Crustaceans, Soy, Wheat, Latex, Gluten-containing sources, Peanuts and Tree Nuts) and do not come in contact with these allergens during the manufacturing or packaging process.

**Conflict Minerals**

Conflict minerals are not used in the formulation of the raw materials or manufacturing of these Mixed4Sure products.

**Bisphenol A (BPA) and Phthalates**

BPA and Phthalates are not used in the formulation of the raw material or manufacture of these Mixed4Sure Pronto products.

**Melamine**

Melamine is not used in the formulation of the raw materials or manufacture of these Mixed4Sure Pronto products.

**Genetically Modified Organisms (GMO)**

The component materials used in the manufacture of these assemblies 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 assemblies that come in contact with the fluid pathway.

**Restriction of Hazardous Substances (RoHS) - EU**

Restrictions on the use of certain hazardous substances in electric and electronic equipment as defined in Directive 2011/65/EU and amendments in force (including Directive (EU) 2015/863).

Based on a review of the final product composition by the raw material manufacturers, there are no RoHS substances known to be present above the declaration threshold in these Mixed4Sure Pronto products.

**Substances of Very High Concern (SVHC)**

As of the date listed on this document, SaniSure does not believe any of the chemicals listed on the attached EU Candidate List of Substances of Very High Concern are present in the Mixed4Sure Pronto products at levels above the declaration threshold.

Sincerely,



Vincent Pimentel

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