	<b>Tygon S3™ E-LFL Manufacturing and Regulatory Information Overview (RIO)</b>	
	<b>REF-960-0006</b>	
	<b>Revision: 4</b>	<b>Effective Date: 05/20/22</b>

## **MANUFACTURE**

### **Country of Origin**

Tygon S3™ E-LFL is manufactured in the U.S.A.

### **Manufacturing Location**

Saint-Gobain Performance Plastics  
 2664 Gilchrist Road  
 Akron, OH 44305  
 USA  
 Tel: +1 (330) 798-9240

### **Materials of Construction**

Tygon S3™ E-LFL is a proprietary polyvinyl chloride (PVC) formulation.

### **Certification**

Standard Certificate of Conformance.

### **Storage Conditions**

No special storage conditions. Products awaiting shipment are stored in ambient lighting, temperature and humidity condition. Ambient storage conditions consist of a cool, dry environment away from direct sunlight and in the original unopened packaging.

### **Shelf Life**

The shelf life of Tygon S3™ E-LFL tubing is two (2) years from the date of manufacture, when stored in the original shipping container under conditions of 0°C (32°F) to 49°C (120°F) and less than 80% Relative Humidity.

## **STANDARDS TESTING**

### **USP Class VI**


Tygon S3™ E-LFL meets the requirements of the USP, Biological Test for Plastics, Class VI.

### **FDA Food**

Tygon S3™ E-LFL complies with the applicable FDA food additive regulations in contact with the following food types: all non-fatty foods, except foods containing greater than 15 percent alcohol (Food Types I, II, IVB, VIA, VIB, VIC {up to 15 percent alcohol}, and VIIB) under condition of use: E through H as described in Table 1 and 2 of 21 CFR 176.170(c). The food shall not be left in the tubing over 8 hours.

### **EU Food**

Tygon S3™ E-LFL complies with relevant requirements of the Framework Regulation (EC) N°1935/2004 and the Plastics Regulation (EU) N° 10/2011 as amended when the article is for repeat use in contact with all aqueous, acidic, and alcoholic foods up to an alcohol content of 20% under the contact conditions that include hot-fill and/or heating up to a temperature T where  $70\text{ °C} \leq T \leq 100\text{ °C}$  for maximum of  $t = 120/2^{(T-70)/10}$  minutes, which are not followed by long term room temperature or refrigerated storage. See the declaration of compliance (DOC) for further information.

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**NSF-51**

NSF-51 listed, manufactured by Saint-Gobain, maximum temperature 165°F.

**PRODUCT STEWARDSHIP**

**BSE/TSE**

Tygon S3™ E-LFL is compliant with EMA/410/01 Rev. 3.

**Latex**

Latex is not used in the manufacture of Tygon S3™ E-LFL. Tygon S3™ E-LFL does not come in contact with latex materials during the manufacturing or packaging process.

**Genetically Modified Organisms (GMO)**

Tygon S3™ E-LFL is manufactured with material(s) derived from soy and may contain GMO. The supplier(s) of those material(s) are not able to confirm the absence of GMO.

**Toxic Compounds**

Toxic compounds such as Polyaromatic hydrocarbons/polynuclear aromatic hydrocarbons (PAH/PNA), 2-mercaptobenzothiazole (2-MBT), benzothiazole disulfide (MBTS) and N-nitrosamines are not used in the formulation or manufacture of this product.

**Melamine**

One of the raw material suppliers has disclosed that they have a statistical surveillance program to ensure material is not above the applicable legal limit of 1ppm.

**Bisphenol A (BPA)**

Bisphenol A is not used in the formulation or manufacture of Tygon S3™ E-LFL.

**Persistent Organic Pollutants**


In accordance with the Stockholm Convention of 2009, EC850/2004, and EU 757/2010, Persistent Organic Pollutants (POP), are not used in the formulation or manufacture of Tygon S3™ E-LFL. This includes, but is not limited to, Perfluorooctanoic acids (PFOA), Perfluorooctane sulfonates (PFOS), Polychlorinated biphenyls (PCB), Dioxins, Furans, and Polyaromatic hydrocarbons (PAH).

**Restriction of Hazardous Substances (RoHS)**

Tygon S3™ E-LFL is in compliance with, and conforms to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the Restriction of the Use of Certain Hazardous Substances in electrical and electronic equipment(EEE) (also called “RoHS 2”) as amended to date and its amendment Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the List of Restricted Substances (also called “RoHS 3”).

**REACH Registration, Evaluation, Authorization and Restriction of Chemicals (EC 1907/2006)**

Tygon S3™ E-LFL has been evaluated against Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation,

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Authorization and Restriction of Chemicals (“REACH”), as amended to date, and in compliance with Article 33 (1).

The product DOES NOT CONTAIN any substances from the Substance of Very High Concern (SVHC) candidate list (Total 223 substances) in concentration above 0.1% weight by weight (w/w).

**Conflict Minerals**

There is no instance of Conflict Minerals, as defined by the Dodd-Frank Act, used in the manufacture of Tygon S3™ E-LFL.

**RESPONSIBILITY**

This Regulatory Information Overview document is intended to provide users of Saint-Gobain Tygon S3™ E-LFL with the information necessary to assess the suitability of these products for use in their intended application.

Saint-Gobain has not run an analysis for concentration levels for the materials listed in the above statements but relies on raw material suppliers and Saint-Gobain manufacturing controls for this information.

The above information does not warrant this product for any particular use or any specific application. It is the responsibility of the customer to conduct testing that is deemed necessary to determine the suitability for the intended use and to comply with all applicable statutory, regulatory, compatibility and industry requirements and standards.

Saint-Gobain believes to the best of its knowledge that the above statements are accurate as of the effective date of this document and the statements and certifications of suppliers or service providers that Saint-Gobain may have relied upon in the preparation of this document. These statements are valid unless superseded by revised statements at a later date.