Regulatory Information Overview

Tygon® A-60-C

Country of Origin

Tygon® A-60-C tubing is manufactured in France.

Manufacturing Location

Saint-Gobain Performance Plastics
34 rue du moulin des Aulnaies, BP14
89120 Charny-Orée-De-Puisaye, France
Telephone (+) 33 (0) 3 86 63 78 78

Material of construction

Tygon® A-60-C tubing is a thermoplastic elastomer.

Site Certifications

Tygon® A-60-C tubing is manufactured in Charny-Orée-De-Puisaye following ISO 9001, ISO 13485, ISO 14001, and OHSAS 18001 standards.

Tygon® A-60-C Shelf Life and Storage

The shelf life of Tygon® A-60-C tubing is 3 years from date of manufacture, provided the product is packaged in the original unopened packaging and is stored under ambient temperature and humidity conditions, protected from sunlight/fluorescent light/UV.

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

Based on information provided by our suppliers, bovine or other animal derived content materials are not used in the raw materials used to manufacture Tygon® A-60-C tubing as defined in specification EMA/410/01 rev.3. Saint-Gobain does not intentionally use, or add, any substances or materials with animal content in the manufacture process that come in contact with Tygon® A-60-C tubing.

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Regulatory Information Overview

GMO substances

The Tygon® A-60-C tubing materials do not contain any GMO substances.

Bisphenol A (BPA)

BPA is not used in the formulation or manufacture of Saint-Gobain Tygon® A-60-C tubing.

Latex, Gluten, and Allergens

Tygon® A-60-C tubing is latex-free and do not come in contact with latex materials during the manufacturing or packaging process. The materials used to manufacture Tygon® A-60-C tubing do not contain allergens as defined by the FDA (Milk, Eggs, Fish, Crustaceans, Soy, Wheat or other Gluten-containing sources, Peanuts and Tree Nuts) and does not come in contact with these allergens during the manufacturing or packaging process.

Food and Beverage Status

Tygon® A-60-C tubing is compliant with FDA regulations CFR 177.2600.

Phthalates

Phthalates are not used in the formulation or manufacture of Saint-Gobain Tygon® A-60-C tubing. These include: di(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), di-n-butyl phthalate (DBP), di-isobutyl phthalate (DIBP), di-iso-decyl phthalate (DIDP), di-iso-nonyl phthalate (DINP), di-n-octyl phthalate (DNOP) and di-n-pentyl phthalate (DNPP). They may be present in a concentration limit of 0.1%.

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

Tygon® A-60-C tubing DOES NOT CONTAIN any of the substances included in the REACH Authorization list (Annex XIV) and Restriction list (Annex XVII). In addition, the product(s) DO NOT CONTAIN any substances from the Substance of Very High Concern (SVHC) candidate list (Total 205 substances) in concentration above 0.1% weight by weight (w/w).

Restriction of Hazardous Substances (RoHS) & Coalition of Northeastern Governors (CONEG)

Tygon® A-60-C tubing is in compliance with, and conform to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011on 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

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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”).

RESPONSIBILITY

This Overview document is intended to provide users of Saint-Gobain Tygon® A-60-C tubing with the information necessary to assess the suitability of these products for use in their intended application.

Saint-Gobain has not run any analysis for concentration levels for the regulatory compliances listed above but has relied on raw material suppliers for this information. It is the responsibility of the customer to determine whether their use of Saint Gobain product is safe, lawful (except as provided in the above certifications) and technically suitable for their intended purpose.

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