SAINT-GOBAIN	**Regulatory Information Overview**	**Réf. :** RIO-5
		Revision : 2
	Versilic® tubing	**Effective Date :** 09/01/2026

Country of Origin
Versilic® products are manufactured in France.

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

Saint-Gobain Performance Plastics
5 rue du Dauphiné
38070 Saint-Quentin Fallavier
Tel (+) 33 (0)4 74 94 82 22

Material of construction
Versilic® products are manufactured with 100% Virgin Synthetic Silicone (proprietary components).

Site Certifications
Charny-Orée-de-Puisaye
ISO 9001 : 2015
ISO 13485 : 2016
ISO 14001 : 2015
ISO 45001 : 2018

Saint-Quentin Fallavier
ISO 9001 : 2015
ISO 13485 : 2016
ISO 14001 : 2015

Versilic® Shelf Life
Shelf life is 5 (five) years from the Date of Manufacture

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

Animal Derivation Materials
This product is not intentionally made or manufactured with animal derived material.

GMO (Genetically Modified Organism) substances
The materials used to manufacture this product are not genetically modified through the use of modern biotechnology.

Bisphenol A (BPA)
BPA is not intentionally added either into the formulation or during the process to produce Saint-Gobain Versilic®, and based on the information provided by our raw material suppliers, we are not aware of above substances being intentionally added into our raw materials.

Phthalates compounds
Phthalates are not intentionally added either into the formulation or during the process to produce Saint-Gobain Versilic®, and based on the information provided by our raw material suppliers, we are not aware of above substances being intentionally added into our raw materials.

DOMINIQUE DUTSCHER SAS

Latex, Gluten, and Allergens

The product is not intentionally made or manufactured with natural rubber latex, gluten and allergens (as defined by the FDA milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans, sesame).

USP<88> Class VI

Versilic® products has met the requirements of the USP <88> Class VI , and/or USP <87>, and/or ISO10993-5

Food contact status

Versilic® products complies with applicable FDA Food Additive Regulations including 21 CFR Part 177.2600

European Pharmacopoeia 3.1.9

Versilic® products meet European Pharmacopoeia 3.1.9.

ISO10993 series

- Genotoxicity, Carcinogenicity, and Reproductive Toxicity:

Versilic® products have met the Sensitization and Irritation test requirements as described in ISO 10993-3, Biological evaluation of medical devices- part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity.

- Hemocompatibility:

The product has met the Hemolysis test requirements as described in ISO 10993-4, Biological evaluation of medical devices- part 4: Selection of tests for interactions with blood.

- Cytotoxicity:

The product has met the Cytotoxicity test requirements as described in ISO 10993-5, Biological evaluation of medical devices- part 5: Tests for in vitro cytotoxicity.

- Irritation and Skin Sensitization:

The product has met the Sensitization and Irritation test requirements as described in ISO 10993-10, Biological evaluation of medical devices- part 10: Tests for irritation and skin sensitization.

- Acute Systemic Toxicity:

The product has met the Acute Systemic Toxicity test requirements as described in ISO 10993-11, Biological evaluation of medical devices- part 11: Tests for systemic toxicity.

Saint-Gobain's customers are responsible for determining that any medical device they manufacture and market that incorporates a Saint-Gobain product, is compliant with each country-specific medical device regulations and has received proper country-specific clearance, certification or registration authorizing the sale of the medical device.

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

The Product is regularly evaluated against Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals ("REACH"). Based on the raw material information provided by our vendors, the Product DOES NOT CONTAIN any of the substances included in the REACH Authorization list (Annex XIV), Restriction list (Annex XVII), and in the Substance of Very High Concern (SVHC) candidate list in concentration above 0.1% weight by weight (w/w), as of the date of this document.

DOMINIQUE DUTSCHER SAS

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

The product is in compliance with, and conform 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) as amended to date. This declaration is based on the raw material information provided by our vendors.

The product has been evaluated against the CONEG Model Toxics in Packaging Legislation. The product(s) referenced DO NOT CONTAIN intentionally introduced lead, cadmium, mercury, hexavalent chromium, phthalates and PFAS in concentration over 100 ppm by weight. This declaration is based on the raw material information provided by our vendors.

RESPONSIBILITY

This Overview document is intended to provide users of Saint-Gobain Versilic® 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.

DOMINIQUE DUTSCHER SAS