



Regulatory Information Overview

Versilic® tubing and molded pieces

Country of Origin

Versilic® products are 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

Versilic® products are manufactured with S60V34B formula (proprietary components).

Versilic® products Shelf Life and Storage

The shelf life of Versilic® products is 2.5 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 Versilic® products 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 Versilic® products.

GMO substances

The Versilic® products materials do not contain any GMO substances.



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Bisphenol A (BPA)

BPA is not used in the formulation or manufacture of Saint-Gobain Versilic® products.

USP Class VI

Versilic® products meet the requirements of the current USP, Biological Test for Plastics, Class VI version 2013.

Latex, Gluten, and Allergens

Versilic® products are latex-free and do not come in contact with latex materials during the manufacturing or packaging process. The materials used to manufacture Versilic® products 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 contact status

Versilic® products meet FDA Regulations CFR 177.2600 .

European Pharmacopoeia 3.1.9

Versilic® products meet European Pharmacopoeia 3.1.9 current Edition.

ISO10993 Testing

Versilic® products meet:

- ISO 10993-3 : Genotoxicity Ames test
- ISO 10993-4 : Hemolysis
- ISO 10093-5 : Cytotoxicity
- ISO 10993-10 : Acute intracutaneous reactivity, delayed contact sensitization
- ISO 10993-11 : Systemic toxicity



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Phthalates

Phthalates are not used in the formulation or manufacture of Saint-Gobain Versilic® products. 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)

The European Union REACH regulation of December 18, 2006 requires companies which manufacture or import chemical substances into the European Union in quantities of one metric ton or more per year to register these substances with the European Chemicals Agency (ECHA). Saint-Gobain Performance Plastics complies with the provisions of REACH where applicable.

Versilic® products do not contain materials described as **Substances of Very High Concern (SVHC)** as defined by the European Union/ECHA.

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

Per RoHS Directive 2011/65/EU, Versilic® products is RoHS-compliant and therefore adhere to the guidelines below:

- Concentration of Lead (Pb), Mercury (Hg), Hexavalent Chromium (CrVI), PBB (Polybrominated Biphenyls) or PBDE (Polybrominated Diphenyl Ethers) in product: Not to exceed 1,000 ppm.
- Concentration of Cadmium in product: Not to exceed 100 ppm individually or for the total incidental content per CONEG requirement limits.

None of the currently listed RoHS exemptions are used in the manufacture of Versilic® products.

RESPONSIBILITY

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