

# TYGON

SAFE SMART SUSTAINABLE



DAIRY

BEVERAGE DISPENSING

FOOD DISPENSING

FOOD PROCESSING



[www.TygonS3.com](http://www.TygonS3.com)

## About the Product Line

As an industry leader in Food & Beverage applications, Saint-Gobain Performance Plastics (SGPPL) has designed a brand-new product line addressing the rising safety concerns about phthalates and the increasing regulatory pressure worldwide.

The Tygon S3™ product line includes the following products:

- Tygon S3™ B-44-3
- Tygon S3™ B-44-4X
- Tygon S3™ B-44-4X I.B.
- Tygon S3™ Silver
- Transflow S3™ M-34-R
- Transflow S3™ Vacuum
- Tygon S3™ E-3603
- Tygon S3™ E-LFL



## Phthalate Regulations

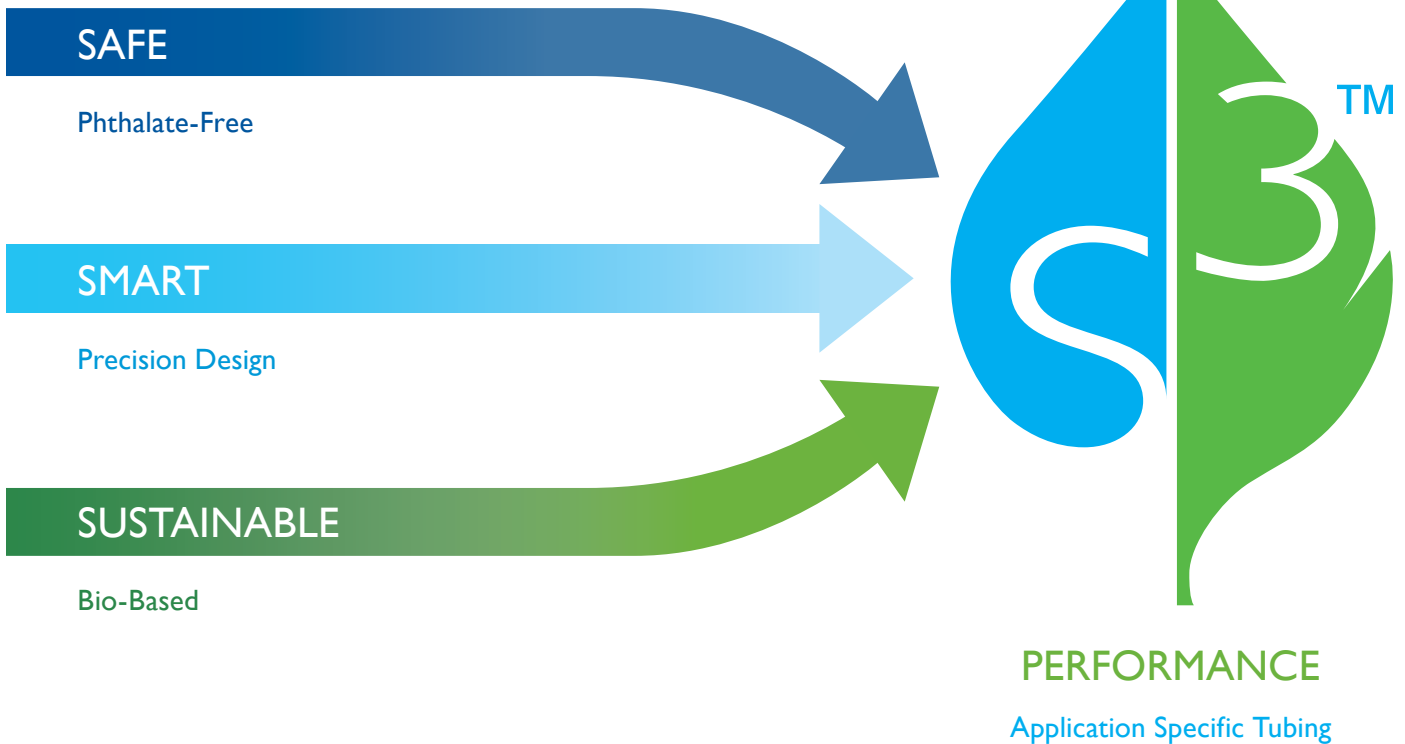
Many tubing products are comprised of a fossil fuel-based phthalate called DEHP (di-2-ethylhexyl phthalate), which is a plasticizer used to give tubing its flexibility, transparency, durability and longevity. Recent studies suggest DEHP may be responsible for negative environmental and human health impacts<sup>[1]</sup>. Already on the EU's REACH candidate list of Substances of Very High Concern (SVHC)<sup>[2]</sup> and California's OEHHA Proposition 65 list of chemicals of concern<sup>[3]</sup>, many industries, consumers and

governments are considering putting limitations on the use of this chemical in certain applications. The use of phthalates as a plasticizer is a rising concern worldwide, and more countries are taking legislative action to limit, prohibit or ban their usage in an increasing number of applications. Phthalates are expected to be limited or prohibited on all direct and indirect food contact regulations.

## Tygon S3™ Benefits

As part of Saint-Gobain's commitment to sustainability, we have reformulated the Tygon® tubing product line and have developed a bio-based, phthalate-free alternative option - Tygon S3™ - to address the needs of new regulatory requirements, while still providing the same level of high performance. Being phthalate-free means the potential human health and environmental impacts during the tubing's use are reduced.

Companies who use Tygon S3™ will have reduced exposure to risk or liability for their business with the anticipated regulation on products containing phthalates like DEHP. Consumers now have the ability to choose a safer, smarter and more sustainable product for their food and beverage dispensing, and dairy and food processing needs. Special instructions have been validated to ensure safe and appropriate use, serving the applications specified. The complete compliance information and use instructions can be found at [www.TygonS3.com](http://www.TygonS3.com).



### References:

<sup>[1]</sup> NIH, Hazardous Substances Data Bank, Bis(2-ethylhexyl) phthalate, <http://toxnet.nlm.nih.gov/cgi-bin/sis/search/r?dbs+hsdb:@term+@rn+117-81-7>

<sup>[2]</sup> ECHA, Candidate List of Substances of Very High Concern for Authorisation, Accessed June 19, 2012

<sup>[3]</sup> State of California EPA OEHHA, Chemicals Known to the State to Cause Cancer or Reproductive Toxicity, March 16, 2012



## The Need for a New Solution

Today, more than ever, product success is built not just on brand quality, but food safety as well.

With the increase in globalization and the growing complexity of supply chains, governments around the world are stepping up the complexity and scope of regulations that apply to food and beverage companies. In the U.S., most notable are two



bipartisan pieces of landmark federal legislation – H.R. 2749, the Food Safety Enhancement Act and S.510, the U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA). Both acts have been crafted to guarantee the U.S. food supply is safe by making businesses responsible for proactively evaluating their food safety standards. To ensure compliance, manufacturers are now being called to

implement written preventative control plans regarding potential hazards that could affect food safety and verify that suppliers – both foreign and domestic – have similar controls in place.

Legislators' concerns stem from rising concerns regarding the possible contamination of food processes. According to the U.S. Centers for Disease Control, each year approximately 76 million Americans – about 25% of the total population – get sick from contaminated food or drinks, resulting in some 300,000 hospitalizations and 5,000 deaths. Two of the primary causes are the growing rate of globalization and increasingly complex supply chains. Where at one time manufacturers had long-standing partnerships with predominantly local ingredient suppliers, companies today can change suppliers several times in a single year and may be working with firms on the other side of the world in order to increase cost efficiencies.

For manufacturers, the goal is to avoid potential contamination and protect their brands from product recalls, which can amount to millions of dollars in lost revenue. The trend in food and beverage recalls is certainly not encouraging, with the number more than tripling since 1999 <sup>[4]</sup>, <sup>[5]</sup>. The financial impact of a recall can be substantial for companies, including removing food from shelves, handling lawsuits, revamping plants and repairing public relations. Recalls not only mean that products are pulled from shelves, but consumer trust in an entire brand portfolio can be at risk. If brands take a proactive stance to ensure that food safety criteria are met, however, this self-regulation can actually build customer goodwill and loyalty, demonstrating that the company is making higher quality and safer products. With consumers increasingly scrutinizing each purchase more closely, they are able to justify paying more for a product if they believe that the product is safer or of higher quality.

With the industry paying ever-closer attention to every element of their processes and supply chain, there is increasingly more interest in employing solutions that leverage the latest advances in material science and R&D to address concerns and maximize productivity.

## Food Safety

Phthalates are commonly used to increase food and beverage tubing's flexibility, transparency, durability and longevity. However, with increasingly stringent legislation, processors anticipate transitioning to equipment that eliminates phthalates altogether. Today, advances in materials science have yielded innovative materials with various performance properties, resulting in tubing solutions that provide dependable food safety and effective performance.

**Tygon S3™ enables food and beverage manufacturers to advance food safety measures without sacrificing performance.**

It is advances such as these that have enabled Saint-Gobain to introduce the next generation of flexible food tubing – Tygon S3™. Formulated with an entirely new kind of plasticizer, Tygon S3™ is completely phthalate-free while still meeting the high performance standards of our popular Tygon® brand. The new solution has been introduced in order to enable food and beverage manufacturers around the world to advance food safety measures without sacrificing performance.



As FSMA and other legislation dictates changes to current standards and reporting structures, new solutions such as Tygon S3™ will continue to help processors guarantee their facilities meet and exceed the expectations of the industry – and most importantly – the end-use consumers.

**Tygon S3™ provides exceptional performance and can be precisely tailored for highly specialized applications.**

### References:

<sup>[4]</sup> Oehl, Frank. "Food Safety's New Regulatory Reality." FoodSafety Magazine, 2010.

<sup>[5]</sup> Food Industry Report, April 15, 2009



## Smart Design

Beyond regulatory compliance, food and beverage manufacturers look to technology solutions that ensure consistent and high performance at every stage of the process. Solutions for product transfer, processing and dispensing are required to meet the highest standards, which may vary widely, not only according to unique ingredients that are transported, but also to the individual application – and which stage in that application – they are employed.

Recognized as an integral and vital component of fluid transport systems, Saint-Gobain's Tygon® tubing has a strong reputation for delivering an uncompromising standard, ensuring optimum performance under the high pressures and temperatures associated with food and beverage processing. The latest evolution of our food and beverage tubing, Tygon S3™ delivers the same performance of Saint-Gobain's Tygon® brand, providing exceptional durability and longevity while meeting the demand for flexible formulation with the ability to be precisely tailored for highly specialized applications.

**Tygon S3™ helps brands reach their sustainability goals to minimize their carbon footprint and inspire confidence from consumers, partners and investors.**

With a wealth of best-practice knowledge and applied expertise, plus an engineering staff with years of combined experience, Saint-Gobain's solutions help processors guarantee their facilities meet and exceed the expectations of the industry – and most importantly – the end-use consumers. Tygon S3™ is a portfolio of proven, advanced solutions to optimize food and beverage plant operations so companies can maximize their profitability and market share. Designed with a deep understanding of these dynamic and highly competitive markets, Tygon S3™ helps food and beverage manufacturers achieve their highest production goals and increase their enterprise value.

## Promoting Sustainability

As food and beverage processors across the globe are increasingly held accountable for the safety of consumables, closer scrutiny will also be paid to other qualities associated with the supply chain, in particular their carbon footprint. Studies show that brands and consumers alike are increasingly aware of a company's sustainability and social responsibility initiatives, and that food and beverage processors can effectively use this information to communicate their commitment<sup>[6]</sup>.

The sustainability of a brand can be measured in many ways, including the reduction of greenhouse gases, minimizing material waste or harmful by-products, or higher efficiency equipment and operations.

As an alternative to phthalates, the Tygon S3™ portfolio uses a bio-based material as a plasticizer, which allows food and beverage manufacturers to strengthen their commitment to sustainability because it is made from a material derived from vegetable oil. With the introduction of this new solution, Saint-Gobain is providing customers with a means to realize their green initiatives and minimize their carbon footprint while simultaneously addressing the safety concerns surrounding phthalates, ultimately helping manufacturers protect their brand integrity and offering peace of mind.



## Safe, Smart, Sustainable

In this increasingly difficult-to-navigate environment, food and beverage processors need to focus on many moving parts. With increasing regulatory watchdog attention paid to food safety, processors must be equipped to keep up with the many different regulatory requirements throughout the world. Quick, cost-effective and globally compliant solutions for food processing applications are needed to ensure product safety and protect brand equity. In addition, these same solutions must maintain high levels of performance and sustainability.

With the advent of Tygon S3™, Saint-Gobain is introducing a single technology innovation that meets this extensive list of performance criteria. By providing a solution that is at once *Safe, Smart and Sustainable*, Saint-Gobain is demonstrating its commitment to supporting the continued success of food processors and increasing their ability to compete in a complex global marketplace.

### References:

<sup>[6]</sup> Forward, Retail <http://www.retailforward.com>, 2008.

## F.A.Q.

### What are plasticizers?

Plasticizers are added to plastics to increase their flexibility, transparency, durability and longevity. The most common plasticizers are phthalate-based.

### Are phthalates dangerous to human health?

Phthalates are a rising concern worldwide, with countries taking legislative action to limit, prohibit or even ban their usage.

The concern is primarily for child-related applications and food contact. Regulation No. 1272/2008/EC considers phthalates toxic for reproduction: "May cause harm to the unborn child" (Repr. Cat. 2 R61) and "Possible risk of impaired fertility" (Repr. Cat. 3 R62). In 2008, the U.S. Consumer Product Improvement Act banned the use of three phthalates in products intended for children under 12.



### What is DEHP?

Di (2-ethylhexyl) phthalate (DEHP) is a colorless, odorless, organic chemical considered one of the most common phthalates. DEHP is widely used as a plasticizer because it is economical and performs well in a variety of different metrics.

### Where is DEHP used?

DEHP is used in a wide variety of applications including medical devices, footwear, electrical cables, packaging and flooring.

### Is DEHP the only phthalate in use as a plasticizer?

While DEHP is the most common phthalate-based plasticizer, there are other phthalate-based plasticizers commonly used to plasticize PVC.

### What is a bio-based plasticizer?

Made from plant extract, bio-based plasticizers are a sustainable resource, contributing to economic development while reducing greenhouse gases and our dependency on petroleum-based substances.



### With which regulatory standards does Tygon S3™ comply?

Tygon S3™ complies with FDA, NSF, 3-A, Japan Food Sanitation Law # 370/1959, REACH, 1935/2004/EC and 10/2011/EU for many foods and beverages. Tygon S3™ tubing products do not contain chemicals listed in California's Proposition 65. For complete compliance information and appropriate use instructions, please refer to the detailed document of compliance. The complete compliance information and use instructions can be found at [www.TygonS3.com](http://www.TygonS3.com).

#### European Union

- **REACH** is the Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals. The main goals of REACH are to ensure a high level of protection of human health and the environment from the risks that can be posed by chemicals, the promotion of alternative test methods, the free circulation of substances on the internal market and enhancing competitiveness and innovation.
- **Regulation 10/2011/EU**, usually known as the Plastics Implementing Measure (PIM) regulation, includes directives for food contact.
- **Regulation 1935/2004/EC**: Reference materials and articles intended to come into contact with food, known as the "Framework Regulation" covering all materials which might come into contact with food. It states that "food contact materials shall be safe. They shall not transfer their components into the food in quantities that could endanger human health, change the composition of the food in an unacceptable way or deteriorate the taste and odor of foodstuffs."
- **Regulation 2023/2006/EC** on good manufacturing practice, defines more specifically the requirements in regards to good manufacturing practice, as required by Regulation 1935/2004/EC. The guidelines for "good manufacturing practice" described in this document apply to plastic materials and articles covered by Regulation 10/2011/EU. "Good manufacturing practice" for production of food contact materials and articles follows a chain beginning at approval and acceptance of the starting materials for polymer production and ending when the materials or articles come into contact with food and meet legal compliance.
- **Tygon S3™ complies with REACH, regulation 10/2011/EU, 1935/2004/EC and 2023/2006/EC under special instructions validated to ensure safe and appropriate use, serving the applications specified. The complete compliance information and use instructions can be found at [www.TygonS3.com](http://www.TygonS3.com).**

#### United States

- The Food & Drug Administration (FDA) regulates substances that come in contact with food. Ingredients must be compliant with the FDA Code of Federal Regulations and regarded as safe.
- 3-A is a symbol that indicates the plastic material meets 3-A Sanitary Standards. 3-A requirements are considered among the best, especially regarding milk and milk products.
- The National Sanitation Foundation (NSF) lists appropriate materials and manufacturing processes for the production of food processing equipment.



- California Proposition 65 requires businesses to notify California residents about significant amounts of chemicals in the products they purchase.
- Tygon S3™ is approved by the FDA (FCN 1126) for use in flexible tubing for food and beverage applications. It is also certified by 3-A Sanitary Standards. The National Sanitation Foundation certified our products under standards NSF-51 and NSF-61. Tygon S3™ does not contain any listed substances under Proposition 65.

#### Japan

- The Ministry of Health, Labor and Welfare enacts the Food Sanitation Law as the comprehensive law for food safety/hygiene. Under the system, only additives designated as safe by the Ministry of Health, Labor and Welfare may be used in foods.
- Article 10 of the Food Sanitation Act provides that additives and preparations and food containing additives shall not be sold, or be produced, imported, processed, used, stored, or displayed for the purpose of marketing, except for cases that the Minister of Health, Labor and Welfare specifies as having no risk to human health by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council, thereby introducing the "positive list" system, in which only those approved "designated additives" are allowed.
- The specification and standard for each substance are set out in the "Specifications and Standards for Food and Food Additives, etc." (Ministry of Health, Labor and Welfare Notification No. 370, 1959, Section 2 Additives) (Latest Revision: 2010, MHLW Notification No. 336).
- Tygon S3™ complies with Japan Food Sanitation Law # 370/1959.

#### Why should I choose this product?

Choose Tygon S3™ to have a positive impact on the planet, to ensure the safety of the products you manufacture or if you want the only available choice for a widely compliant and bio-based phthalate-free plasticizer product. Whether you are concerned by your customers' perception of phthalate-based products in your process or want to align your products to your company values, our bio-based product line is the only available choice. Tygon S3™ guarantees you a high level of performance.



#### Does that mean your current products are not safe?

No, our current products are compliant with the regulations of the regions in which they are sold.

#### Are there similar products available on the market?

This is the only product using a bio-based, phthalate-free plasticizer that performs as well as Tygon®.

#### How do the Tygon S3™ products perform as compared to the phthalate-containing products?

Our studies demonstrate that the new products perform similarly to the existing ones. Differences in chemical resistance to concentrated acids and bases can be found at [www.TygonS3.com](http://www.TygonS3.com).

#### Where is Tygon S3™ manufactured?



The only choice for phthalate-free flexible tubing

## TYGON B-44-3

Clear, flexible tubing for beverage transfer

- Clear as glass for easy visual monitoring of flow
- Lightweight and flexible for easy, quick installation
- Non-wetting properties allow easy cleaning and complete drainage

Tygon S3™ B-44-3 is specially formulated for transferring a wide variety of beverages including soft drinks, fruit juices, flavored teas and bottled water. In virtually all cases, Tygon S3™ B-44-3 will not affect the taste or odor of product transferred through it, while its excellent non-wetting properties facilitate complete drainage and permit simple flush-cleaning.



## TYGON B-44-4X

Ensuring a bacterial-free fluid path in a wide variety of food processing applications

- Smooth, nonporous bore will not trap particulates or promote bacterial growth
- Excellent alternative to rigid piping systems
- Excellent resistance to harsh alkaline cleaners and commonly used sanitizers

Producers of food, milk and dairy products insist upon Tygon S3™ B-44-4X for dependable performance in countless filling, draining, transfer and processing applications. Its smooth, nonporous bore inhibits particle entrapment, promoting a sanitary fluid path by minimizing potential for bacterial growth. It is resistant to harsh alkaline cleaners and is equally unaffected by commonly used sanitizers.



[www.TygonS3.com](http://www.TygonS3.com)

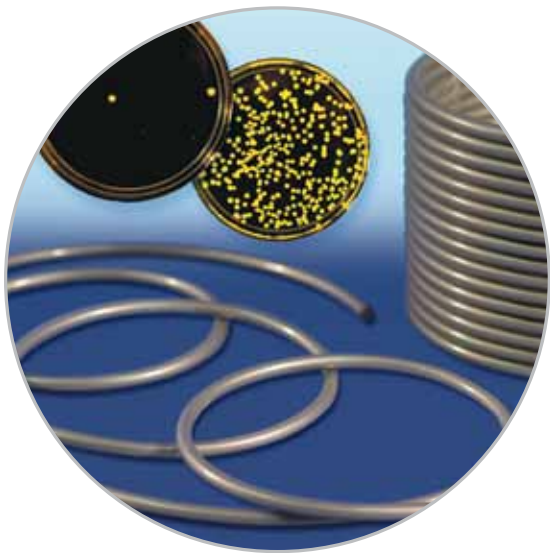
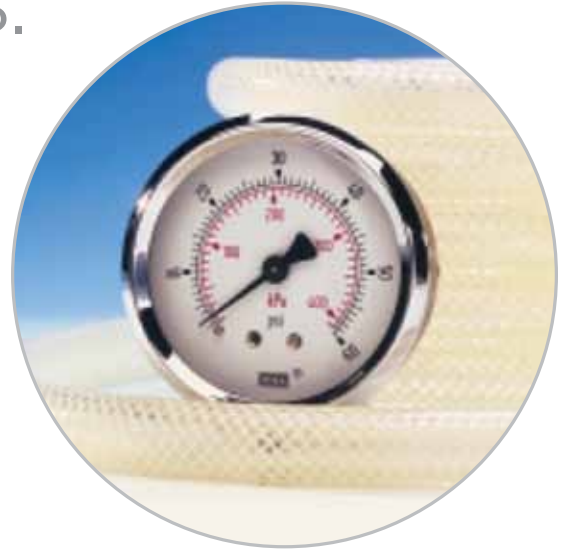
The compliance status of each product according to the marketing region can be found on [www.TygonS3.com](http://www.TygonS3.com). Please refer to the detailed document of compliance of each product for a complete compliance information and appropriate use instruction. The complete compliance information and use instructions can be found at [www.TygonS3.com](http://www.TygonS3.com).

# TYGON B-44-4X I.B.

Reinforced to provide increased pressure capability, it's the most flexible reinforced tubing available

- Handles four times the pressure of non-reinforced tubing
- Clear wall enables visualization of fluid flow
- Connects easily to ReSeal® sanitary fittings

Lightweight and easy to handle, Tygon S3™ B-44-4X I.B. goes into service quickly. It readily curves around corners and obstructions, requiring a minimum of couplings and fittings. Its flexibility can save up to one-third the footage and much of the labor required to install rigid stainless steel, glass tubing or piping.



# TYGON SILVER

Decreases bacterial growth and provides added value

- Plasticizer-free inner bore
- Reduces formation of biofilm and mildew
- Inhibits growth of microbes

Our custom compounding capabilities allow us to produce antimicrobial versions of many of our tubing products, including Tygon®. Tygon S3™ Silver is formulated with an antimicrobial compound on the inner surface at the point of fluid contact; the tubing outer surface can be treated in cases where bacteria buildup on the O.D. is a concern.



The only choice for phthalate-free flexible tubing

# TRANSFLOW M-34-R

The leading choice in dairy tubing

- Crystal clarity permits visual inspection of milk flow
- Smooth, nonporous bore resists buildup
- Durability for long and reliable service

Transflow S3™ tubing is clear, allowing for immediate visual inspection and verification of cleanliness. Its smooth, nonporous inner surface reduces the occurrence of buildup from butterfat, milkstones and milksoil and can help to eliminate the possibility of bacteria growth within the milk transport line.



# TRANSFLOW VACUUM

Dairy and vacuum applications

- Holds full vacuum at room temperature
- Will not crack and age like rubber tubing
- To be used in conjunction with Transflow S3™ M-34-R

Transflow S3™ Vacuum tubing is ideally suited for supply air transport. The smooth inner surface is less susceptible to particle entrapment, which can restrict air flow, while crystal clarity permits detection of equipment deficiencies such as backflow of milk into the air lines. Transflow S3™ Vacuum tubing is designed to work in tandem with Transflow S3™ M-34-R to provide a vacuum tube and easy fluid flow within the milking process.



[www.TygonS3.com](http://www.TygonS3.com)

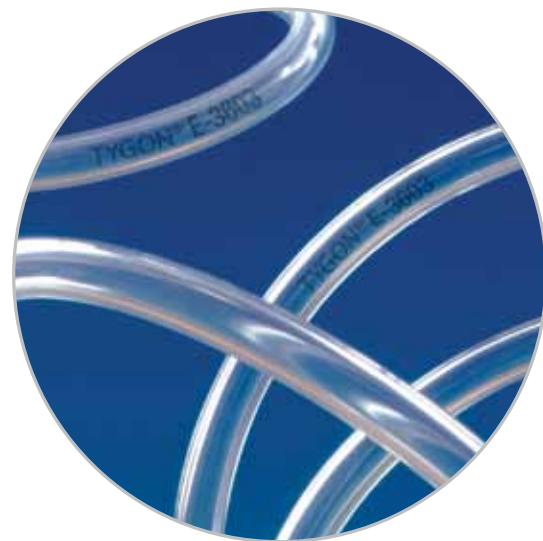
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# TYGON S<sup>3</sup>™ E-3603

Non-DEHP tubing for laboratory, food & beverage and vacuum applications

- Outstanding chemical resistance
- Increases productivity in peristaltic pumps – outlasts the original R-3603 by 3 to 1
- Non-oxidizing and non-contaminating
- Meets USP Class VI criteria

Tygon S<sup>3</sup>™ E-3603 tubing is specially formulated for resistance to flex-fatigue and abrasion. In many peristaltic pump applications it will outlast the original R-3603 by 3 to 1. As a tubing for instrumentation connection, vent, drain and other general laboratory applications, Tygon S<sup>3</sup>™ E-3603 tubing offers superior life, which minimizes the labor and expense of replacement. It can be sterilized through conventional autoclave methods (steam 30 minutes at 1 bar, 121° C), and EtO (Ethylene Oxide).



# TYGON S<sup>3</sup>™ E-LFL

Non-DEHP pump tubing for laboratory, food & beverage, and biopharmaceutical applications

- Longest flex life of any clear Tygon® tubing — reduces downtime caused by pump failure
- Can be autoclaved — suitable for high purity applications
- Extremely low particle spallation — reliable for sensitive-fluid applications
- Meets USP Class VI, ISO 10993 criteria

Crystal-clear Tygon S<sup>3</sup>™ E-LFL tubing is formulated specifically for use in peristaltic pump applications. The new Tygon S<sup>3</sup>™ E-LFL non-DEHP tubing has even longer pump life not only at 0 bar but also at back pressure of up to 1,7 bar.



## Tygon® Manufacturing Facilities

### Saint-Gobain Performance Plastics

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## Tygon® Sales Offices

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The Saint-Gobain Performance Plastics Group manufactures a variety of plastics products, including Tygon® Beverage Tubing. Saint-Gobain is actively pursuing strategies to reduce their environmental impact and to increase the sustainability of its operations and products. Saint-Gobain has a corporate sustainability strategy for reducing energy use, water use and waste, and has conducted Life Cycle Assessments (LCAs) of many of its products in order to better understand and to improve these products. Life Cycle Assessment is a method for identifying the environmental impacts of a product, process or activity over its entire lifespan, including extraction and processing of raw materials, manufacturing, transportation and distribution, installation, use, maintenance, and end of life including recycling and final disposal.



[WWW.TYGONS3.COM](http://WWW.TYGONS3.COM)

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**WARNING:** The content of Saint-Gobain Performance Plastics tubing materials is not certified by the FDA for implant devices and is neither designed nor intended to be used in medical applications involving permanent implantation in the human body or permanent contact with body fluids or tissues. Failure to comply with this warning may lead to serious bodily injury or death.

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**IMPORTANT:** It is the user's responsibility to ensure the suitability and safety of Saint-Gobain Performance Plastics tubing for all intended uses. Laboratory and clinical tests must be conducted in accordance with applicable medical device regulatory requirements in order to determine the safety and effectiveness for use of tubing in any particular application.

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**6-Month Limited Warranty:** For a period of 6 months from the date of first sale, Saint-Gobain Performance Plastics Corporation warrants this product to be free from defect in manufacturing. Saint-Gobain Performance Plastics' only obligation will be to provide replacement tubing for any portion proven to have such a defect, or at Saint-Gobain Performance Plastics' option, to refund the purchase price thereof. User assumes all other risks, if any, including the risk of injury, loss or damage, whether direct, consequential or incidental, arising out of the use, misuse, or inability to use this product. Saint-Gobain Performance Plastics DISCLAIMS ALL IMPLIED warranties of merchantability AND fitness for a particular purpose.

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**NOTE:** Saint-Gobain Performance Plastics Corporation does not assume any responsibility or liability for any advice furnished by it, or for the performance or results of any installation or use of the product or of any final product into which the product may be incorporated by the purchaser and/or user.