DURLON®
SEALING SOLUTIONS

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SEALING SOLUTIONS FOR THE

Pharmaceutical Industry

We Succeed **When you Succeed.**

Our Vision

Evolution isn't a choice in today's business landscape, it's the only way to succeed.

Progress relies on everything moving forward; from people to machinery to production. Everything must flow.

As we engineer our way to a better world, we are breaking down barriers, making sure each process is in place, always reflecting and improving. We are experts at delivering the best sealing solutions to help our customers unlock their highest potential.

Our global community of industry leading specialists drive our innovative production and materials to consistently raise the bar.

Whether through the stress of everyday use, or specialized applications and high-temperature environments, liquid or gas, our products deliver sustainable integrity.

At Durlon®, we succeed when you succeed.

DURLON®
SEALING SOLUTIONS

Sealing Solutions for the **Pharmaceutical Industry**

The pharmaceutical industry is a vital component of the healthcare sector, responsible for the development, manufacturing, and distribution of medications and other healthcare products.

The products produced by the pharmaceutical industry are numerous and varied. They include prescription drugs, over-the-counter medications, vaccines, medical devices, and diagnostic tests, among others.

Prescription drugs and vaccines are perhaps the most well-known and profitable product of the pharmaceutical industry. These drugs are typically developed through a rigorous process of research and development, clinical trials, and regulatory approval.

Over-the-counter medications are another important product of the pharmaceutical industry. These are medications that can be purchased without a prescription, typically for the treatment of mild to moderate symptoms. Common over-the-counter medications include pain relievers such as aspirin and ibuprofen, as well as cold and flu medications, allergy medications, and digestive aids.

The manufacturing process for these products involves several stages, each of which plays a critical role in ensuring the quality, safety, and efficiency of the final product.

The first stage of the manufacturing process is research and development. This stage involves the discovery and development of new drugs, medical devices, or diagnostic tests. Scientists and researchers work to identify potential new products and conduct preclinical studies to determine their safety and efficacy. Once a potential product has been identified, clinical trials are conducted to further evaluate its safety and efficacy in human patients.

Once a product has been approved for manufacturing, the next stage is formulation development. This stage involves the development of the formula or recipe for the final product. The formulation must be carefully designed to ensure the appropriate dosage, bioavailability, and stability of the product. Various ingredients are combined in a specific manner to produce the final product.

The next stage is manufacturing. This stage involves the actual production of the product in large quantities. The manufacturing process can vary depending on the type of product being produced, but typically involves a series of steps, including mixing, granulation, compression, and coating. The manufacturing process is carried

out in a sterile environment to ensure the quality and safety of the final product.

Quality control is a critical aspect of the manufacturing process. Throughout the manufacturing process, various tests are conducted to ensure that the product meets strict quality standards. These tests may include physical, chemical, and microbiological tests. Samples of the product are taken at various stages of the manufacturing process and tested to ensure that they meet the required specifications.

Packaging and labeling is the next stage of the manufacturing process. Once the product has been manufactured and tested, it must be packaged and labeled appropriately. This involves the selection of appropriate packaging materials, such as bottles, tubes, or blister packs, and the application of labels that include important information such as dosage instructions, storage requirements, and expiration dates.

The final stage of the manufacturing process is distribution. Once the product has been packaged and labeled, it is distributed to healthcare providers, pharmacies, and other distribution channels. The product must be stored and transported appropriately to ensure that it remains safe and effective until it reaches the end user.

Innovative products
Unparalleled service

Polytetrafluoroethylene (PTFE) gasket material

Aggressive chemicals, high pressures and extreme temperatures can all create challenging conditions. Durlon® designs and manufactures high-performance sealing solutions for a wide range of chemical processing applications, including pumps, valves, flange joints, pipelines, and more.

Durlon® filled PTFE gaskets/sheets are exclusively manufactured at Triangle Fluid Controls Ltd. in Belleville, Ontario, Canada. Our compression molded and skived manufacturing process allows for the best control of physical properties and performance characteristics compared to other manufacturing processes. With unique formulas of fillers, Durlon® PTFE products can meet your tough chemical applications and engineering specifications.

PTFE (polytetrafluoroethylene) has excellent chemical resistance and its unique properties lends itself well for use in a variety of industrial, manufacturing, and engineering facilities. The superb chemical resistance and tolerance to vast temperature gradients has not only improved the efficiency of many industries, but the safety for the employees that work around those conditions as well.

General properties of PTFE

- Excellent chemical resistance
- Wide range of service temperature
- Excellent dielectric properties
- Non-stick, low friction
- No embrittlement or aging
- Smooth surface finish can be achieved
- Non-wetting
- Outstanding corrosion protection
- Electrical insulation
- High thermal stability and flame resistance
- Resistance to weathering
- Food grade compliant

Durlon® 9000 & 9000N PTFE

Various shapes of inorganic fillers have been homogeneously blended with pure PTFE resins to give Durlon® 9000 its physical and mechanical properties. It is suitable for use in steel flanges and will not exhibit the cold flow problems associated with virgin PTFE or the hardness problems of some other filled PTFE products. It cuts easily and separates cleanly from flanges after use. Durlon® 9000 is for use in general industrial applications where resistance to highly aggressive chemicals is required. In addition, the shape of the fillers does not allow wicking which can cause corrosion on flange surfaces.

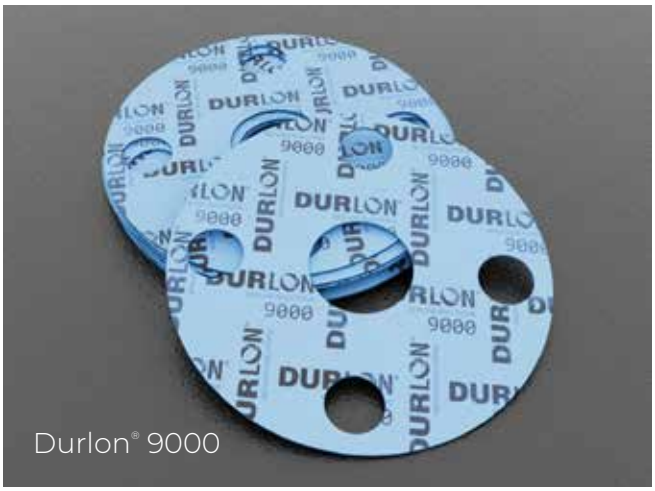
PTFE is highly resistant to corrosion due to its chemical inertness. Unfortunately, that same chemical inertness prevents PTFE from being cross-linked like elastomers and is subject to the phenomenon of cold flow – otherwise known as “creep”. To reduce and diminish cold flow, additives are introduced during the preparation of PTFE compounds. Glass fillers found in Durlon® 9000 and 9000N gaskets, not only reduce creep but also maintain chemical inertness against aggressive and caustic chemicals but are still considered safe for use by food, drug, and medical services.

Certifications

Durlon® 9000 – API 6FA Fire Test, TA-Luft (VDI 2440), Pamphlet 95 (Chlorine Institute), FDA Compliant, USP Class VI Certified, ABS-PDA Certified, EC 1935/2004 Compliant.

Durlon® 9000N – FDA compliant, ABS-PDA Certified, USP Class VI Certified.

Durlon® Product Recommendations



Durlon® 9000

Durlon® 9000N

Durlon® 9200


Durlon® 9600

Durlon®
Joint Sealant

Durlon® 9645

Physical Properties & Certifications

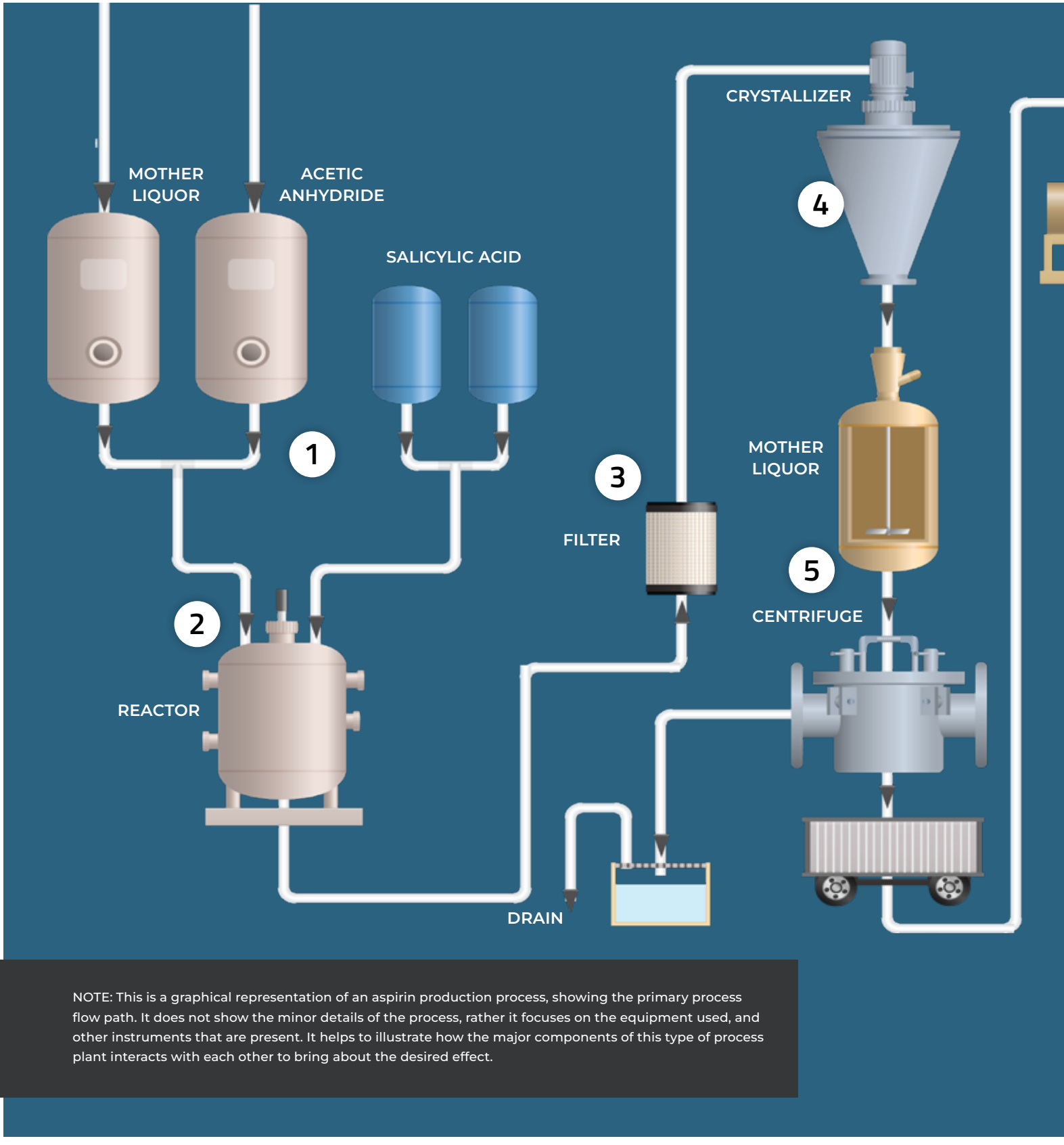
Physical Properties	9000/9000N	9200	9600	Joint Sealant	9645
Composition	Inorganic Filler / Pure PTFE Resins	Barium Sulfate Filler / Pure PTFE Resins	100% Pure Expanded PTFE	100% Pure Expanded PTFE	Modified PTFE with rigid PTFE core
Color	Blue/White	Off White	White	White	White
Temperature: Min Max Continuous, Max	 -212°C (-350°F) 271°C (520°F) 260°C (500°F)	 -268°C (-450°F) 260°C (500°F) -	 -268°C (-450°F) 316°C (600°F) 260°C (500°F)	 -268°C (-450°F) 260°C (500°F) -	 -260°C (-436°F) 260°C (500°F) -
Pressure, max, bar (psi)	103 (1,500)	83 (1,203)	200 (2,900)	200 (2,900)	60 (870)
Density, g/cc (lbs/ft^3)	2.2 (138)	-	0.9 (56.2)	0.65 (40.6)	1.3 (81)
Compressibility, %	8-16	4-10	50-60	-	>44
Recovery, %	40	40	>10	-	>6.3
Creep Relaxation, %	30	15	22	-	<26
Tensile Strength, MPa (psi)	13.8 (2,000)	14 (2,030)	20 (2,800)	-	-
Sealability ASTM 2378 (Nitrogen)	 0.01 cc/min	 -	 -	 -	 -
pH range, Room Temperature	 -	 -	 -	 0-14	 -

Style	Certifications
9000	Passed API 6FA, 3rd Edition Fire Test, Met requirements of 121°C (250°F) for USP for Plastic Class VI, Conforms to required 21 CFR 177.1550 for FDA, TA-luft (VDI Guideline 2440) approved material, ABS-PDA & Pamphlet 95 approved material - chlorine institute, (EC) 1935/2004 & EU (10/2011) approved material.
9000N	USP Class VI Met requirements for Plastic Class VI - 121°C (250°F), Approved material - chlorine institute for ABS-PDA & Pamphlet 95, (EC) 1935/2004 & EU (10/2011), and conforms to FDA requirements of 21 CFR 177.1550 for food and drug contact
9200	TA-luft (VDI Guideline 2440), BAM Oxygen Service, ABS-PDA & Pamphlet 95, (EC) 1935/2004 & EU, Blow-Out & DVGW approved materials, and conforms to FDA requirements of 21 CFR 177.1550 for food and drug contact.
9600	Conforms to FDA requirements of 21 CFR 177.1550 for food and drug contact. Approved material for ABS-PDA. RoHS Reach Declaration compliant.
Joint Sealant	RoHS Reach Declaration, and conforms to FDA requirements of 21 CFR 177.1550 for food and drug contact.
9645	Conforms to FDA requirements of 21 CFR 177.1550 for food and drug contact, TA-luft (VDI Guideline 2440) approved material.

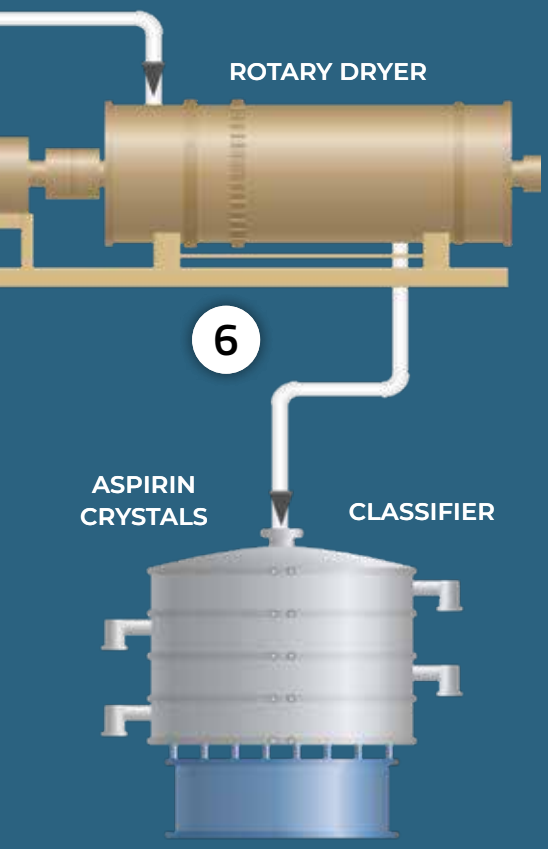
Note: ASTM properties are based on 1/16" sheet thickness, except ASTM F38 which is based on 1/32" sheet thickness. This is a general guide only and should not be the sole means of accepting or rejecting this material. The data listed here falls within the normal range of product properties, but should not be used to establish specifications limits nor used alone as the basis of design. For applications above Class 300, contact our technical department.

Warning: Durlon® gasket materials should never be recommended when both temperature and pressure are at the maximum listed. Properties and applications stated are typical. No applications should be undertaken by anyone without independent study and evaluation for suitability. Never use more than one gasket in one flange joint and never reuse a gasket. Improper use or gasket selection could cause property damage and/or serious injury. Data reported is a compilation of field testing, field service reports and/or in-house testing. While the utmost care has gone into publishing the information contained herein, we assume no responsibility for errors. Specifications and information contained within are subject to change without notice. This edition cancels and obsoletes all previous editions.

Aspirin Production Process Flow Diagram



NOTE: This is a graphical representation of an aspirin production process, showing the primary process flow path. It does not show the minor details of the process, rather it focuses on the equipment used, and other instruments that are present. It helps to illustrate how the major components of this type of process plant interacts with each other to bring about the desired effect.



Durlon® Product List

1. 9000, 9000N, 9600
2. 9000, 9000N, 9600
3. 9000, 9000N, 9600
4. 9000, 9000N, 9600
5. 9000, 9000N, 9600
6. 9000, 9000N, 9600

The production of aspirin typically involves the following steps:

1. MIXING OF SALICYLIC ACID WITH ACETIC ANHYDRIDE: Salicylic acid and acetic anhydride are mixed in a reactor. This reaction is catalyzed by a small amount of concentrated sulfuric acid.

2. HEATING THE MIXTURE:
The reaction mixture is heated for about 20-30 minutes at a temperature of 80-85°C to ensure completion of the reaction and evaporation of excess acetic anhydride and acetic acid.

3. COOLING AND FILTRATION:
The mixture is then cooled to room temperature, and then filtered to remove any impurities that may have formed during the reaction.

4. CRYSTALLIZATION:
The filtrate is subjected to crystallization by adding a suitable solvent, typically water, to allow the pure aspirin to crystallize out of the solution.

5. SEPARATION OF CRYSTALS:
The aspirin crystals are separated from the mother liquor using a centrifuge. A centrifuge is a machine that uses centrifugal force to separate substances of different densities. In this case, the aspirin crystals are denser and will settle at the bottom of the centrifuge tube.

6. DRYING AND PACKAGING:
The aspirin crystals are washed and dried again to remove any remaining moisture and impurities. The final product is then packaged into tablets, capsules, or other suitable dosage forms.

The core of the Durlon® brand is to provide fluid sealing solutions that make sense, both financially and strategically. We accomplish this through process-oriented design, sector-specific knowledge, and extensive testing. Our goal is to ensure performance and safety while adhering to the quality management system registered to ISO 9001:2015.

At Durlon®, we offer specially developed sealing solutions tailored directly to your specific needs.

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