



DURLON®

FDA COMPLIANT PRODUCTS

Durlon understands every product used in food and beverage applications needs to meet strict international safety and hygienic regulations. They are designed with CIP (Cleaning In Place) and SIP (Sterilization In Place) in mind, thus eliminating the need for different materials. They comply with a growing number of national and international rules and regulations, like FDA, USP, NSF and 3-A standards. They have achieved numerous certifications for WRAS approved Material, USP Class VI, FDA and conform to FDA 21 CFR 177.2600 rubber articles intended for repeated use.

Our products are used in mixers, homogenizers and blenders along with other food processing machinery.

All of our raw materials and finished products are tested in our In-House laboratory to insure our materials meet our high quality standards throughout the production process. That's why our sealing solutions provide exceptional performance in food and beverage applications, delivering unsurpassed product integrity, safety and reduced downtime.

Our products are designed to reduce failures, thereby stopping contamination, loss of production and possible personal injury. Safety is our number one priority at Durlon. Our dedication is not only for our workers and factories, it is in the products we produce. Safety truly is important at Durlon.



FDA COMPLIANT PRODUCTS

The following products conform to FDA Requirements



Durlon® 8500 is a high-performance compressed gasket material designed for applications in various process industries, such as pulp and paper, food and beverage, pharmaceutical, hydrocarbon, chemical, refinery, and general industry. It proves effective with a wide range of substances, including oils, water, steam, new-generation refrigerants, dilute acids and alkalis, and various other liquids and gases. Additionally, this material fully adheres to FDA standards.



Durlon® 9000 is intended for application in process piping and equipment across diverse sectors such as chemical, pulp and paper, food and beverage, and general industrial settings where resilience to extremely corrosive chemicals is essential. Additionally, the filler's shape prevents wicking, mitigating the risk of corrosion on flange surfaces and ensuring adherence to FDA requirements. Moreover, it has garnered multiple certifications.



Durlon® 9000N is designed for utilization in process piping and equipment within chemical, pulp and paper, food and beverage, and other general industrial applications, where there is a need for resistance to extremely aggressive chemicals. Additionally, the filler's configuration prevents wicking, which could otherwise lead to corrosion on flange surfaces, and it complies with FDA requirements.



Durlon® 9002, an enhanced version of the initial glass-filled formula, has been specifically tailored to address rigorous cryogenic requirements. It successfully underwent testing with both gaseous and liquid oxygen under challenging conditions, and in accordance with BAM standards. Furthermore, it complies with LOX Mechanical Impact Sensitivity (ASTM G86 & ISO 21010), exhibiting zero reactions out of twenty tests (0/20) at a test reaction frequency of 0%. Importantly, Durlon® 9002 is formulated to adhere to FDA requirements.



Durlon® 9200, a filled PTFE gasket material, is crafted for applications involving aggressive chemicals, encompassing caustics, hydrogen peroxide, sodium hypochlorite, nitric acid, liquors, and pulp and paper digesters. Its versatility extends to chemical, pharmaceutical, and plastics industries, handling substances such as butadiene, hydrofluoric acid, vinyl chloride, methyl methacrylates, and styrene. Widely employed in railroad tank-car applications, it is suitable for scenarios demanding resistance to highly aggressive chemicals. Additionally, it adheres to FDA requirements.



Durlon® 9600, crafted exclusively from pure PTFE resins, stands as an expanded PTFE gasket intended for deployment in process piping and equipment across chemical, pulp and paper, food and beverage, and various general industrial applications demanding resistance to highly aggressive chemicals. Notably, Durlon® 9600 excels in sealing flanges with irregular surfaces, addressing concerns like cold flow issues linked with virgin PTFE or the hardness problems associated with certain filled PTFE products. With outstanding sealability, ease of cutting, and clean separation from flanges post-use, this material is also fully compliant with FDA standards.

Durlon® PTFE FDA Compliance

Please be advised that our Durlon® PTFE products as listed below are compliant to FDA regulations indicated.

CFR Title 21 - Food and Drugs Part # Section #	Durlon® 9000, 9000N, 9002			Durlon® 9200			Durlon® 9600		
	Branding	Fillers	Finished Product	Branding	Fillers	Finished Product	Branding	Fillers	Finished Product
Part 175 - Indirect Food Additives: Adhesives and Components of Coatings Section 300 - Resinous and polymeric coatings	✓	n/a	✓	✓	n/a	✓	n/a ¹	n/a	n/a ¹
Part 177 - Indirect Food Additives: Polymers Section 1500 - Perfluorocarbon Resins	n/a	n/a	✓	n/a	n/a	✓	n/a	n/a	✓
Part 177 - Indirect Food Additives: Polymers Section 2600 - Rubber articles intended for repeated use	n/a	✓	✓	n/a	✓	✓	n/a	n/a	n/a
Part 178 - Indirect Food Additives: Polymers Section 3297 - Colorants for polymers	n/a	n/a	✓	n/a	n/a	✓	n/a	n/a	✓
✓ = Compliant to stipulated regulation n/a = not applicable to stipulated regulation 1 = Durlon 9600 is supplied unbranded as standard offering									

CFR Title 21 - Food and Drugs Part #177 - Indirect Food Additives: Polymers Section #1550 - Perfluorocarbon Resins Extraction Test (2 hours)	Durlon® 9000, 9000N, 9002		Durlon® 9200		Durlon® 9600	
	Fluoride Extractives	Total Extractives	Fluoride Extractives	Total Extractives	Fluoride Extractives	Total Extractives
Distilled Water	✓	✓	✓	✓	✓	✓
50% Ethanol	✓	✓	✓	✓	✓	✓
n-Heptane	✓	✓	✓	✓	✓	✓
Ethyl Acetate	✓	✓	✓	✓	✓	✓
✓ = Pass						