



September 28, 2020

**RE: 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 Durlon 9000N Durlon 9002			Durlon 9200W Durlon 9200Y			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 <sup>1</sup>	n/a	n/a <sup>1</sup>
Part 177 – Indirect Food Additives: Polymers Section 1550 – 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	✓ <sup>2</sup>	n/a	n/a	✓
	✓ = Compliant to stipulated regulation n/a = not applicable to stipulated regulation 1 = Durlon 9600 is supplied unbranded as standard offering 2 = Does not apply to Durlon 9200Y								

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

Regards,



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