



# Triangle Fluid Controls Ltd.

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February 4, 2016

## 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 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 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,



Chett Norton, C.E.T.  
Engineering & QA Manager  
Triangle Fluid Controls Ltd.



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## **Declaration of Compliance for materials and articles intended to come into contact with food<sup>1</sup>**

Triangle Fluid Controls Ltd  
399 College St. E.  
K8N 5S7 Belleville, Ontario  
Canada

Declares that the product described below:

### **Durlon® 9000**

complies with the relevant requirements as laid down in:

- Framework Regulation (EC) 1935/2004 (dated 27-10-2004).
- EU Commission Regulation (EU) 10/2011 relating to plastic materials (tested according to EC Directive 97/48/EC; Migration testing (2<sup>nd</sup> amendment of 82/711/EEC) and EC Directive 85/572/EC; List of simulants).

It has been manufactured in accordance with the relevant requirements of Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

The chemical composition of product Gaskets (Durlon 9000® samples) consists of:

- The following substances subject to limitations and/or specifications:

<b>Name of substance</b>	<b>CAS no.</b>	<b>FCM</b>	<b>Limitations / Specification</b>
Tetrafluoroethylene	116-14-3	281	SML = 0.05 mg/kg

This material does not contain intentionally incorporated dual use additives which are subject to disclosure of adequate information as described in Annex VIa of Directive 2007/19/EC.

<sup>1</sup> Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEEC – Article 16.

Migration tests of the above-mentioned product are performed according to Commission Regulation (EU) No 10/2011, directive 97/48/EC and directive 85/572/EEC and have shown that under these conditions of use migration limits were not exceeded:

- type of food intended to come in contact with material/article: all types of foodstuffs
- Shelf-life and material/article temperature: any food contact condition
- Possible treatment of material/article:
- Surface/volume ratio: 6 dm<sup>2</sup> / kg food

Test results are available on request.

Traceability of the product is ensured according to Regulation (EC) No. 1935/2004 This Declaration of Compliance is valid for the product delivered by us as specified above.

The information included in this document is valid from stated version date until this document is superseded.

Because of possible changes in the underlying legislation and regulations, as well as possible changes in our products, we cannot guarantee that the status of this document will remain unchanged. We, therefore recommend our customers to verify the regulatory status periodically. It will be renewed in all cases where the previous conformity is no longer ensured.

The Commission Regulation (EU) 10/2011 provides a guideline for the selection of test conditions to be used for various food products. According to that and under considerations of the food contact stated, the product complies with the stipulations of this Regulation regarding the packaging of food products to be packed. The user shall verify himself that the product is suitable for the intended food to be packed beyond the stipulations of the Regulation.

Done at,

**TRIANGLE FLUID CONTROLS LTD.**

Place: Belleville, ON CANADA

Date: January 16, 2014

Signature:



Chett Norton, C.E.T.

