# EPN-4590



#### GENERAL INFORMATION

Category: Sterile sampling bags

Family: Twirl'Opaque

Lifespan: 5 years

#### **TECHNICAL DESCRIPTION**

Twirl'Opaque bags have a convenient and easy-to-use closure system and are designed for lightsensitive samples. They are made of black resin and a flexible and durable plastic.



### SPECIFIC INFORMATION

#### ITEM

ITEM	Bag
Material :	Polyethylene blend
Color :	Black
Dimension :	114 x 229 mm / 4.5 X 9 po
Thickness :	2.5 mil.in/ 63.5 micron / 0.0635 mm
Total volume :	650 ml / 22 oz
Utility volume :	390 ml / 13 oz
Printing type :	Writing area
Opening system :	Perforated line
Closing system :	Attachment with 2 round wires
Sterile :	Yes
End of product life :	Recyclable

## PACKAGING INFORMATION

Outer box dimension : (W x D x H)	16.38 po x 9.63 po x 9.63 po 42 cm x 24 cm x 24 cm
Box weight:	10.00 LB / 4.54 KG
Conditioning:	1000 (2 x 500)
Storage condition:	Store in a dry place at room temperature

### OTHER



# AVAILABLE DOCUMENTS

Data Sheet	Certificate of Compliance
Certificate of Analysis	Safety Data Sheet (SDS)
Certificate of Sterility	Pyrogen Declaration
DNase/RNase	

Reach out to us for additional resources, if applicable to this product.

## DECLARATION

CFIA	LABPLAS sampling bags are a solution that may be used in the CFIA Preventive Control Plan (PCP) for the seven principles of the HACCP system. The PCP is a Canadian federal initiative, under the Safe Food for Canadians Regulations (SFCR).
EU	The materials used to manufacture LABPLAS sampling bags meet, where applicable, the Eu No10/2011 standards for food contact with respect to particle migration.
DNase-free	This product is DNase-free. Sensitivity of 10-7 Kunitz units/µL
RNase-free	This product is RNase-free. Sensitivity of 10-9 Kunitz units/µL.
FDA	The plastic film used in the manufacture of the LABPLAS sampling bag meets the requirements of the Food and Drug Administration Regulation [ 21 CFR 177.1520 (b), (c)2.1, (c)3.1a, (c)3.2a, and 170.39, 174.5 (a), 178.2010 (b), 178.3297 (c), and 178.3860], provided that the sampling bag is not in contact with an alcoholic product and that the conditions of use comply with section C to G of table 2 of 21 CFR 176.170 (c).
Pyrogens	This product is non-pyrogenic at the endotoxin limit of 2.15 EU/device. Non- pyrogenicity is supported by endotoxin testing of randomly selected samples using the Limulus amebocyte lysate (LAL) gel assay according USP-NF <85> and <161> guidelines.
Sterile	Sterility is provided by dry heat during extrusion of the plastic at temperatures exceeding 428 F. The approach ensures a sterility assurance level (SAL) of 10-3. Continued process effectiveness is demonstrated through periodic sterility testing. Sterility testing follows the USP-NF <71> guideline.

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