

## PRODUCT SPECIFICATION AND COMPLIANCE CERTIFICATE

We would like to acknowledge the following:

- All Twirl'em® and Secure-T bags® are made of low density virgin polyethylene (LDPE) manufactured in accordance with FDA (Food and Drug Administration) specifications.
- Tube is extruded and biologically inert. Product has a 5-year sterility warranty.
- Product should not be used at temperatures greater than 80°C (176°F) or temperatures lower than -100°C (-148°F), as advised by our raw material suppliers. In any case, it is strongly recommended to only use products for transportation or sampling. Product is not meant to be used as packaging.
- Tolerance for thickness is  $\pm 10\%$  mil.
- Tolerance for width is  $\pm 1/8$ "
- Tolerance for length is  $\pm 1/4$ "
- Sterility is ensured by extrusion temperatures exceeding 220°C which will eliminate any present bacteria. Only once the bag is opened by tearing along the perforated line is the bag's interior susceptible to possible contamination from its present environment.
- To further document this process random lots are analyzed based on "USP 40 – Sterility testing" for:
  - 1) Total aerobic bacteria detection
  - 2) Total anaerobic bacteria detection
  - 3) Yeast detection
  - 4) Mould detection
- These analyses are periodically performed at our in-house laboratory at Labplas.

### ***FDA REGULATION & EU REGULATION No. 10/2011***

All TWIRL'EM® sampling bags and Secure-T® blender bags comply to the applicable regulations of the Food and Drug Administration (21 CFR 177.1520 (c)3.1a, (c)3.2a and 178.2010) and to the European Union No 10/2011 regulation on plastics and articles intended to come in contact with food, subject to certain types of migration limitations and labeling requirements.

Furthermore, all TWIRL'EM® sampling bags and Secure-T® blender bags manufactured by Labplas are also a solution which could be used in the CFIA Prevention Plan targeting HACCP critical points, a Canadian federal initiative from the *Safe Food for Canadians Regulations*.

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**HEAVY METALS**

No antimony, arsenic, barium, cadmium, chromium, lead, nickel, selenium, silver, zinc or mercury, among others, is used in the formulation of Labplas' products. No heavy metal is intentionally introduced into the material's formulation and does not exceed 100 ppm in compliance with CONEG and RoHS model requirements.

**ANIMAL DERIVATIVES AND GMO**

Labplas' products are formulated without any tallow-based derivative material and therefore comply with USDA regulations for exposure to transmissible spongiform encephalopathy (TSE) / bovine spongiform encephalopathy (BSE). Product is GMO free.

**LATEX, RUBBER, PHTHALATES**

Product is free of any rubber or latex components and no phthalates are intentionally added or used as additives or raw material in the manufacture of this product.

**ADDITIVES**

No bisphenol A, antimicrobial, fungicidal, pesticidal or similar additives is used as additive or raw material in the manufacture of this product. Product is free of melamine and melamine was not intentionally added or used as an additive or raw material in the manufacture of this product.

**REACH REGULATION**

Labplas does not deliberately add any of the current substances (as of 25-06-2020) in the EU's Candidate List of Substances of Very High Concern (SVHC).

**RNASE / DNASE / PYROGENS**

Product is RNase/DNase and pyrogen free.

This statement is based on information provided by our raw material suppliers. We do not intentionally add any of these substances in our manufacturing processes. If you have any further questions or require further testing documentation, please contact our Customer Service Department for assistance.



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