

PRODUCT SPECIFICATION AND COMPLIANCE CERTIFICATE

We would like to acknowledge the following:

- All Twirl'em® and Secure-Tbags® 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.
- Tolerance for thickness is $\pm 10\%$ mil.
- Tolerance for width is $\pm 1/8$ "
- Tolerance of length is $\pm 1/4$ "
- Sterility is assured due to extrusion temperatures exceeding 220°C which will eliminate any present bacteria. During manufacturing all bags are sealed at both top and bottom in a continuous format before being cut into individual bags. This method assures that the bag's interior will never come in contact with its surroundings. 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, based on the USP 39 – Sterility testing, random lot samples are analyzed for:
 - 1) Total aerobic bacteria detection
 - 2) Total anaerobic bacteria detection
 - 3) Yeast detection
 - 4) Mould detection
- These analyses are performed by a Microbiologist and periodically; samples are analyzed in parallel with an independent laboratory to validate our sterility testing methods.

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.

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.

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ANIMAL DERIVATIVES

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 AND BIOCIDES

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. Biocidal activity tests have been conducted on sponges and results are showing no biocide presence.

REACH REGULATION

Labplas does not deliberately add any of the current substances (as of 7th of July 2017) in the EU's Candidate List of Substances of Very High Concern (ASVH).

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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Charles Paquette, Quality Coordinator