

Annette Roy, Regulatory

Product Name: Micrewtube® Catalogue No.: T338-5S

This document replaces any previous version

1. **Product Description:**

1.5ml Micrewtube [®] :	Sterile, conical bottom tube with lip seal screw
	cap. Caps screwed on.

2. Packaging:

> Case: 10 packages of 50 units / 500 units per case

3. **Product Specifications:**

- ➤ Material:
 - Polypropylene tube
 - Polyethylene cap
- Certified RNase, DNase, Pyrogen and DNA Free
- Gamma radiation sterilized at a SAL of 10⁻³; specified dose between 6.5 kGy and 13.5 kGy
- Temperature range: -196°C to +100°C
- Tubes have white marking areas
- Centrifuged up to 20 000 g

4. **Standards and Conformity:**

- > ISO 2859-1: Sampling and inspection procedures
- Resin conforms to FDA 21 CFR 177.1520 > FDA:
- ➤ USP: Resin conforms to USP Class VI
- > CONEG / RoHS: Plastics and colorants are in conformity with
 - CONEG / RoHS standards for heavy metals
- **REACH (SVHC):** Plastic is in conformity to REACH standards
- ► LATEX: Material is Latex Free
- **BSE / TSE:** Material is BSE / TSE Free

5. **Quality Assurance:**

- Clear, no presence of contamination in plastic
- Visual attributes
- Volume measurements
- Closure verification
- Leak proof testing in vacuum at 71.3cm Hg
- Gas phase of Liquid Nitrogen resistance



port Technical Data Sheet

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6. Traceability:

Lot No. Composition: 8 to 9 digits

> The lot number can be found in one or all of these locations:

- 1. On exterior case label
- 2. On label inserted inside the master case
- 3. On the inner bag

7. Storage Conditions:

- Store at room temperature in normal warehouse conditions
- Avoid temperature variations and humidity
- Protect from any possible contamination
- > Protect from any damage to the packaging which could compromise the product sterility

8. Recommended Use:

- > Verify proper cap closure when using biohazard material and / or chemical reagents
- > Follow chemical resistance chart recommendations
- > For use in automated equipment, follow the equipment manufacturer's instructions
- > Should be used only in the gas phase of Liquid Nitrogen

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