LIST BIOLOGICAL LABORATORIES, INC.

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Product #154B

CERTIFICATE OF ANALYSIS
Toxin B Toxoid from *C. difficile*
(formaldehyde inactivated Toxin B from *C. difficile*)
Lot #1541A1B

Contents:

Each vial, when reconstituted with 500 µl of sterile purified water, contains 100 µg of toxoid in 0.1 M Histidine, 0.1 M Sodium Chloride, pH 6.5 with 5% Trehalose. **Handle product gently; do not vortex.**

Concentration:

Protein concentration is determined by a modification of the method of Bradford[1] using bovine serum albumin as the standard.

Purity:

This product has been tested for endotoxin levels and was found to be acceptable.

Toxicity:

Toxoid is produced from Toxin B of *C. difficile* by inactivation with formaldehyde. The resulting toxoid is essentially nontoxic. At 50.0 µg/ml, the toxoid has no detectable cytotoxicity in a cell rounding assay using human foreskin cells when compared to Toxin B. At the highest dose tested (50.0 µg/mouse), mice injected intraperitoneally showed no toxic signs during the seven days of observation.

Packaging and Storage:

This product is supplied as a lyophilized powder, sealed under vacuum. Store at 2-8°C prior to reconstitution. Aliquot and freeze this product at -20°C to store following reconstitution.

Handling:

Good laboratory technique should be employed in the safe handling of this product. This requires observing the following practices:

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1. **Wear appropriate laboratory attire including a lab coat, gloves and safety glasses.**

2. **Do not mouth pipette, inhale, ingest or allow to come into contact with open wounds. Wash thoroughly any area of the body which comes into contact with the product.**

3. **Avoid accidental autoinoculation by exercising extreme care when handling in conjunction with any injection device.**

4. **This product is intended for research purposes by qualified personnel only. It is not intended for use in humans or as a diagnostic agent. List Biological Laboratories, Inc. is not liable for any damages resulting from the misuse or handling of this product.**

FOR RESEARCH PURPOSES ONLY. NOT FOR HUMAN USE.

Reference:

1. Bradford, M.M. (1976) *Anal. Biochem.* **72**, 248-254.

Production: TP Date: 2/8/10 Management: NT Date: 2/8/2010 QA/QC: CL Date: 2/8/10