

CERTIFICATE OF ANALYSIS Toxin B Toxoid from C. difficile (formaldehyde inactivated Toxin B from C. difficile) Lot #1541A1A

Contents

Each vial, when reconstituted with 100 μ l of sterile purified water, contains 20.0 μ g of toxoid in 0.1 M Histidine, 0.1 M Sodium Chloride, pH 6.5 with 5% Trehalose. Handle the product gently; do not vortex.

Concentration

Protein concentration was determined by absorbance at 280 nm using an extinction coefficient of 1.4 for a 1 mg/ml solution.

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 μ g/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 μ g/mouse), mice injected intraperitoneally showed no toxic signs during the seven days of observation.

Packaging/Storage

This product is supplied as a lyophilized powder, sealed under vacuum. Store at 2-8°C prior to reconstitution.

Handling

Good laboratory technique should be employed in the safe handling of this product. Wear appropriate laboratory attire including a lab coat, gloves and safety glasses. Nitrile gloves are recommended for use when handling lyophilized material.

This product is intended for research purposes by qualified personnel. 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.

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QA/QC: 19 Date: 01/29/2021

