

# HUGEL, INC.

## Material Safety Data Sheet (MSDS)

**1. Product:** Botulax® 100U (Botulinum Toxin Type A)

**Company Identification:**

HUGEL, INC. 23, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-dok, Korea

**2. Composition, Information on Ingredients:**

100units of Clostridium Botulinum Toxin Type A, 0.5mg of Human Serum Albumin, 0.9mg Sodium Chloride

**3. Hazardous Identification:** CAS #93384-43-1;<0.002% wt

**4. First Aid Measures:**

For eye contact, immediately flush the eyes with water for 5 ~10 minutes. Consult a physician immediately. For skin contact, wash the skin with soap and water. Launder clothing before reuse. For ingestion, consult a physician immediately and induce vomiting or aspirate stomach contents as soon as possible in a hospital emergency room.

**5. Fire Fighting Measures:**

The material is non-flammable. There are no Known unusual fire or explosion hazards.

**6. Accidental Release Measures:**

During normal patient use, any spilled material should be wiped up and the waste disposed of as medical waste. For large quantity releases, such as at manufacturing or distribution centers, contain the spill and neutralize all contaminated services and equipment using either exposure to sodium hypochlorite or autoclaving. Sodium hypochlorite in concentrations of 0.5% or greater (equivalent to a 1:10 dilution of household bleach) may be used to bathe all surfaces exposed to botulinum toxin for a period of five minutes. Following this, the product is rendered safe and the materials may be disposed

through standard methods. For spills onto surface areas, the contaminated surface should be thoroughly sprayed or rinsed for five minutes with a 0.5% sodium hypochlorite solution, then wiped dry. Autoclaving may be applied to botulinum toxin contaminated material which is in solution or to which the autoclave steam has access. Autoclaving at 121°C for 30 minutes or greater will render the product safe.

## **7. Handling and Storage:**

See the product information described on the package insert for proper information on handling and storage. Do not store with food.

## **8. Exposure Control and Personal Protection:**

There are no engineering controls or respiratory protection required for regular handling of individual vials. Universal precautions as recommended by the Centers for Disease Control (CDC) should be implemented during medical procedures involving the injection of the product. Wash hands thoroughly after handling. No eating, drinking or smoking in or around the use area.

## **9. Physical and Chemical Properties:**

The product is soluble in water. The specific gravity of the product is approximately 1.1. There is no data for this product concerning vapor pressure.

The product appears as a residue inside the vial. There is no odor with the product.

## **10. Stability and Reactivity:**

Stability and biological activity of the product is influenced by factors such as heat, salts, acids, bases, organic solvents, physical and/or chemical environments, photooxidation, and irradiation. The product does not polymerize and there are no materials to avoid, which could result in a reaction.

## **11. Toxicological Information:**

Based on toxicological studies, it has been estimated that the human LD50 by injection is approximately 2800 Units, equivalent to 28 individual vials of Botulax® (Botulinum Toxin Type A)

Purified Neurotoxin Complex (100 Units) for a 70 kg adult.

When injected intramuscularly, Botulinum Toxin Type A has been shown to be teratogenic or to have embryocidal effects in some animal species.

Botulax® should be administered to pregnant women only if clearly needed and only if the potential benefit justifies the potential risk to the fetus.

Women of childbearing age should handle this product with care and observe all precautionary handling information.

Studies in animals have not been performed to evaluate the carcinogenic potential of Botulax®.

The product is not structurally related to any known carcinogens. The clinical experience with

Botulax® (Botulinum Toxin Type A) since 2007 has provided no evidence of carcinogenicity.

In addition, in vitro and in vivo mutagenicity and genotoxicity studies showed no carcinogenic potential.

## **12. Ecological Information:**

There is no information available for the product.

## **13. Disposal Considerations:**

All vials, including expired vials, and equipment or materials used with the drug should be disposed of carefully as is done with all medical waste. For disposal of multiple vials, contact Hugel for further information.

## **14. Transport Information:**

This product is considered a 'Biological Product' for transportation purposes. The product is not regulated as a hazardous material by the US DOT, Canadian TDG, or the European Union ADR for road/ rail transportation purposes and is not regulated as a hazardous material for air transportation by IATA guidelines.

## **15. Regulatory Information:**

**TSCA (Toxic Substances Control Act):** Components of this product are listed on the TSCA Inventory.

**CERCLA (Comprehensive Environmental Response, Compensation, and Liability Act):** This product contains no components subject to reporting or notification requirements.

**SARA Title III (Superfund Amendments and Reauthorization Act):**

**311/312 Hazard Categories:** Immediate Health, Chronic Health

**313 Reportable Ingredients:** None

**WHMIS (Workplace Hazardous Materials Information System - Canada):** Not Regulated (Product is regulated by the Food and Drugs Act)

#### **16. Other Information:**

The preceding information is based on available data and is believed to be correct. However, no warranty is expressed or to be implied regarding the accuracy of this information, the results to be obtained from the use there of or the hazards connected with the use of the material. Since the information contained herein may be applied under conditions beyond our control and with which we may be unfamiliar, Hugel does not assume any responsibility for the results of its use.