SOLSTICE NEUROSCIENCES	Material Safety Data Sheet	
40 General Warren Blvd. Malvern, PA 19355 1-267-620-8000	**MYOBLOC®/NEUROBLOC®**	
	Issued: June 2009	Revision: 2.0
Emergency Telephone Numbers	Transportation	1-800/424-9300 (Chemtrec)
	International	01-202-483-7616

SECTION 1: Chemical Product and Company Information

Common Name
Myobloc®/Neurobloc® - Botulinum Toxin Type B Injectable Solution.

Use
Therapeutic biological product for administration to patient.

SECTION 2: Composition/Information on Ingredients

Chemical Component	CAS #	EINECS #	Percent (%)
[1]Botulinum Toxin Type B	93384-44-2	297-255-5	< 0.00001
Sodium chloride	7647-14-5	231-598-3	<1
Sodium succinate	150-90-3	205-778-7	<1
Human Serum Albumin	9007-83-4	None	<0.1
Purified water	7732-18-5	231-791-2	>98

[1]5000 Units/mL; one Unit contains approx. 0.008 to 0.014 ng or 38 to 71 ng/mL (<0.1µg/mL)

SECTION 3: Hazards Identification

Target Organ
Nervous system, immune system.

Route of Exposure
Skin contact (through abraded skin), eye contact, inhalation, accidental ingestion and injection.

SECTION 4: First Aid Measures

Eyes
Immediately flush eyes thoroughly with water for 5-10 minutes; notify supervisor and medical personnel if redness, irritation, or neurological effects develop.

Skin Contact
Immediately wash skin thoroughly with soap and water; notify supervisor and medical personnel if redness, irritation, or neurological effects develop.

Inhalation
Seek medical attention if breathing difficulties develop.

Ingestion
CALL PHYSICIAN OR POISON CONTROL CENTER for most current information. DO NOT induce vomiting. Get immediate medical attention.

SECTION 4: First Aid Measures

Notes to Physician
Signs and symptoms may not be apparent immediately after overexposure (effects may have delayed onset). An antitoxin is available in the event of immediate knowledge of an overexposure. The antitoxin will not reverse any botulinum toxin-induced muscle weakness or paralysis already apparent by the time of antitoxin administration.

In the United States a licensed bivalent (Type A and Type B) antitoxin, consisting of a refined and concentrated liquid preparation of horse (equine) globulins modified by enzymatic digestion, supplied as a FDA licensed product in single dose vials, containing 7,500 International Units (equivalent to 2381 U.S. Units) of Type A and 5,500 International Units (equivalent to 1839 U.S. Units) of Type B antitoxin, is available from the Centers for Disease Control (CDC) for treatment of poisoning. Because of its limited use and relatively short expiration date, it is stored strategically at CDC quarantine stations in major airports around the nation to ensure delivery to any location in the United States within hours. The mechanism for requesting antitoxin is initiated through state or local health departments. The decision to dispense the antitoxin is made by CDC medical epidemiology staff after discussion with the treating physician. Involvement of CDC and the state health departments fulfills the mission of surveillance and detection in protection of public health. Physicians requesting botulinum antitoxin should contact the CDC at 770-488-7100.

SECTION 5: Fire Fighting Measures

Flammability/Explosivity
Not flammable/explosive.

Extinguishing Media
For packaging material, use water fog or fire extinguishing media suitable for Class B fires (e.g., dry chemical, carbon dioxide or foam).

Special Fire Fighting Procedures
Wear appropriate personal protective equipment. Decontaminate all surfaces and equipment potentially contacted by product.

SECTION 6: Accidental Release Measures

In case of a spill or a release, take precautions to minimize worker exposure. Absorb spilled liquid with appropriate media and place absorbents into a suitable waste container for disposal. Rinse spill area with 10% caustic solution (e.g., >0.25N sodium hydroxide or potassium hydroxide) or treat exposed surfaces with >0.1% sodium hypochlorite solution (1:10 dilution of household bleach), or equivalent, for >30 minutes; follow with a water rinse. Responders should wear gloves, protective eyewear (i.e., safety glasses with side-shields or goggles), and protective clothing (i.e., lab coat or similar disposable garment) while cleaning up the spill. Follow Federal, state and local laws for disposal.

SECTION 7: Storage and Handling

Store at 2° - 8°C (35.6° - 46.4°F) in containers that are appropriately labeled. Protect from light. Wear proper personal protection, if warranted. Avoid inadvertent self-inoculation when handling hypodermic needles. Dispose of needles properly. Regularly decontaminate work areas according to Section 6. Wash hands thoroughly after handling.

SECTION 8: Exposure Controls/Personal Protection

Occupational Exposure Limit
None identified.

Eyes
Safety glasses with side shields or splash goggles.

Skin
Lab coat, nitrile, latex or rubber gloves; wash hands following handling, before eating, drinking and at the end of each workshift.

Inhalation
Respiratory protection is not needed during routine handling of this product.

Ventilation and Engineering Controls
No special requirements are needed during routine handling of this product.

SECTION 9: Physical and Chemical Properties

Physical State	Liquid
Color	Clear, colorless to light yellow
Odor	No odor
Boiling Point/Melting Point	100 °C/0 °C (for water)
Percent Volatility	Not available
Specific Gravity	~ 1 g/cm^3
Molecular Weight	Approximately 700,000 (for botulinum toxin type B and associated proteins)
Solubility	Not applicable
Viscosity	Not available
pH	5.6
Evaporation Rate (Butyl Acetate = 1)	Not available

SECTION 10: Stability and Reactivity

Stability
Stable.

Hazardous Polymerization
Will not occur.

Incompatibilities
None expected.

Hazardous Decomposition Products
None expected.

SECTION 11: Toxicological Information

Each unit (U) represents the amount of botulinum toxin type B that corresponds to the LD50 in mice after intraperitoneal administration. As each company's toxicity testing protocols are different, one should not compare or convert units obtained. Nevertheless, it has been suggested that the acute lethality of botulinum toxins in mice and humans are similar. It also has been suggested that intravenous or intramuscular administration (and intraperitoneal administration by inference) is about 10 times more potent than inhalation exposure and about 1000 times more potent than oral exposure (presumably due to differences in bioavailability).

Systemic absorption of product from accidental inadvertent injection or contact with abraded skin may cause neurological or immunogenic effects. Inhalation exposure from uncontrolled spills of >1 L may cause similar effects.

SECTION 12: Ecological Information

Product is unlikely to cause a concern to the environment.

SECTION 13: Disposal Considerations

Dispose of waste in accordance with appropriate Federal, state and local regulations or applicable governmental requirements.

SECTION 14: Transportation Information

This product is not considered hazardous as defined by 49 CFR 172.101 by the US Department of Transportation (DOT) or International Air Transport Association (IATA).

SECTION 15: Regulatory Information

EPA Designations
None identified.

OSHA Designations
This product contains Human Serum Albumin. In the absence of an FDA certificate of analysis validating the sterility of this component, the requirements stated under OSHA's Bloodborne Pathogens Standard are applicable.

TSCA
Myobloc®/Neurobloc® is considered a "drug" as defined by the Federal Food, Drug and Cosmetic Act (21 USC 321 et. seq.); therefore, it is not a chemical substance under TSCA (40 CFR 720.3 (e)).

SARA
Not subject to the reporting requirements and there are no Threshold Planning Quantities for this product.

California Prop. 65
No component of this product is listed.

SECTION 16: Other Information

Prepared By: **Solstice Neurosciences, Inc**

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