

MATERIAL SAFETY DATA SHEET

Section 1 – Identification of the Substance and Company

Product Name: Tetanus and Diphtheria Toxoids Adsorbed
Synonyms: None
Chemical Family: N/S
Intended Use: Vaccine

Company: MassBiologics
Address: 460 Walk Hill Street
Mattapan, MA 02126
617-474-3000

In case of Emergency, contact: 1-800-457-4626

Section 2 – Hazards Identification

Signal Word: Warning
Hazard Statement: The product is a vaccine that is non-toxic and non-pathogenic. It contains chemically inactivated toxoid proteins that were purified from bacterial cultures. It is not considered to be toxic for humans.
EU Classification: None required
EU Hazard Symbol: None required
EU Risk Phrases: None required
EU Safety Phrases: None required

Section 3 – Composition / Information on Ingredients

Ingredient(s):	CAS #	EC #	% (by wt)
Tetanus Toxoid	Not Assigned	Not Assigned	0.0008 g %
Diphtheria Toxoid	Not Assigned	Not Assigned	0.0008 g %
Aluminum Phosphate	7784-30-7	232-056-9	0.4 g %
Sodium Phosphate	7601-54-9	231-509-8	N/A
Aluminum Chloride	7446-70-0	231-208-1	N/A
Thimerosal	54-64-8	200-210-4	≤0.002 g%
Formaldehyde	50-00-0	200-001-8	<0.02 g%

Section 4 – First Aid Measures

Eye Contact

May cause eye irritation, immediately flush eyes thoroughly with water for at least 15 minutes; seek medical assistance if irritation persists.

Skin Contact

Remove all contaminated clothing and rinse area thoroughly with soap and water for 15 minutes; seek medical assistance if irritation develops or persists.

Inhalation

Remove person to fresh air. Seek medical attention if breathing becomes labored.

Ingestion

Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.

Medical Conditions Aggravated by Exposure

The purified protein components contained in this product are generally not considered to cause disease in humans; although pain, tenderness, erythema, induration, pruritus, swelling and warmth, peripheral are possible at the injection site.

Notes to Physician

Wash and clean injection site.

Section 5 – Fire Fighting Measures

Flammability/Explosively

Not considered to be a fire hazard, although the packaging is combustible. Not considered to be explosive.

Extinguishing Media

Aqueous solutions are non-flammable. Use suitable extinguishing media (e.g., water, alcohol foam, dry chemical, CO2) for surrounding fire.

Special Fire Fighting Procedures

For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product, since toxic, corrosive or flammable vapors might evolve from fires involving product and associated packaging, full protective clothing and a self-contained breathing apparatus are recommended for firefighters or other qualified persons. Decontaminate all equipment after use and if possible, contain and collect firefighting water for later disposal.

Hazardous Combustion Products

None known from product, although toxic, corrosive or flammable thermal decomposition products from packaging are possible.

Section 6 – Accidental Release Measures

Spill Protection Equipment

Wear appropriate protective clothing consistent with the degree of hazard.

Procedures to be followed in Case of Leak or Spill

Surround spill using spill pillows or other inert absorbents. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container suitable for disposal. Dispose of material in a manner that is compliant with federal, state and local laws. Take precautions to prevent entry into waterways, sewers, or surface drainage systems.

Section 7 – Handling and Storage

Storage

Keep in original container, Store at 2-8 degrees C. Do Not Freeze.

Disposal

Dispose of used vial and unused product as a biomedical waste.

Section 8 – Exposure Controls / Personal Protection

Occupational Exposure Limit / Occupational Exposure Category or Band

None currently established by OSHA, NIOSH, or ACGIH.

Engineering Controls

None required for normal handling.

Eye Protection

Eye protection is not needed under normal and intended conditions of product use.

Respiratory Protection

A respirator is not needed under normal and intended conditions of product use.

Skin Protection

Skin protection is not needed under normal and intended conditions of product use.

Other

Wash hands, face and other potentially exposed areas immediately after handling material (especially before eating, drinking, or smoking). Decontaminate all protective equipment after use. Always exercise extreme care when working with sharps/needles/syringe.

Section 9 – Physical and Chemical Properties

Appearance:	Homogenous milky white suspension (after shaking)
Physical State:	Liquid
Odor:	N/A
Molecular Weight:	N/A
pH:	6.0
Boiling Point:	N/A
Melting Point:	N/A
Vapor Pressure:	N/A
Flash Point:	N/A
Flammability:	N/A
Relative Density:	N/A
Partition Co-efficient:	N/A
Auto ignition Temperature:	N/A
Solubility in Water:	N/A
Other Solubility:	N/A
Evaporation Rate:	N/A
Specific Gravity:	N/A
Vapor Density:	N/A
Percent Volatile:	N/A

Section 10 – Stability and Reactivity

Stability:	Chemically stable
Hazardous Polymerization:	Not expected to occur
Hazardous Decomposition Products:	Not expected to occur
Conditions to Avoid:	Do Not Freeze
Materials to Avoid:	None known

Section 11 – Toxicological Information

Acute Toxicity: Product contains inactivated bacterial protein and is not pathogenic. Adverse health effects are considered unlikely when the product is used as a vaccine or administered according to label directions.

Repeat Dose Toxicity: Not considered to be toxic for humans

Target Organs: No data available

Irritation/Sensitization: No data available

Genotoxicity: No data available

Carcinogenicity: No data available

Reproductive and Developmental Toxicity: No data available

Section 12 – Environmental Information

No studies identified. No known significant effects or critical hazards. Local regulations and procedures should be consulted prior to environmental release.

Section 13 – Disposal Considerations

The disposal method for rejected products/returned goods must ensure that they cannot be resold or reused. Dispose of wastes in accordance with prescribed federal, state, and local guidelines.

Section 14 – Transport Information

The MSDS should accompany all shipments for reference in the event of spillage or accidental release only authorized persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous good for transport.

Transport information: Transportation and shipping of this product is not restricted. It has no known significant hazards requiring special packaging or labeling for air, maritime, US or European ground transport purposes.

Section 15 – Regulatory Information

This MSDS complies with the requirements under 29 CFR 1910.1200 and EU guidelines.

OSHA Hazard: None required.

Canada - WHMIS Classifications: Not regulated.

California Proposition 65: Not regulated.

SARA 313: Not listed

CERCLA: Not listed

RCRA: Not listed

TSCA: Not listed

Other: Not listed

Section 16 – Other Information

Sources of Key Data Used to Compile MSDS

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