

US - OSHA SAFETY DATA SHEET

Issue Date 01-Nov-2015 Revision. 3 MassBiologics Document Number MSDS-28 Rev 3

*This sheet is prepared in accordance with 29 CFR §1910.1200 (g)(2) and Appendix D***1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING****Product identifier****Product Name** Tetanus and Diphtheria Toxoids Adsorbed**Other means of identification****Product Information**

Single dose vials of sterile injectable vaccine packaged in a carton of ten vials with a paper product insert containing prescribing information

Synonyms

Td, or Td vaccine, Tetanus vaccine, Tetanus shot

Recommended use of the chemical and**restrictions on use Recommended Use** Active routine and booster immunization for the prevention of tetanus and diphtheria in persons 7 years of age and older. Post-exposure tetanus prophylaxis in management of unclean or non-minor wounds.**Uses advised against** Not available.**Details of the supplier of the safety data sheet****Supplier:** MassBiologics, 460 Walk Hill St, Mattapan, MA 02126, USA**Emergency telephone number**

(+1) 617 474 3000 or (+1) 800 457 4626

2. HAZARDS IDENTIFICATION**Classification****Health Hazards**

Not classified.

Physical hazards

Not classified.

OSHA Regulatory Status

This product is a vaccine licensed for use in humans by the United States Food and Drug Administration and is safe for consumers when used according to the label directions.

Label elements Emergency Overview

Normal precautions common to safe handling and storage of non-hazardous goods should be used

Appearance White, cloudy or milky suspension when agitated to resuspend the white precipitate.

Physical state Liquid with a gel precipitate. **Odor** Not available.

Hazards not otherwise classified (HNOC)

Not classified as a hazardous substance.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms Tetanus and Diphtheria Toxoids Adsorbed

Chemical Name	CAS No.	Weight-%
Tetanus Toxoid Adsorbed ¹	N/A	c. 50%
Diphtheria Toxoid Adsorbed ²	N/A	c. 50%
Water	7732-18-5	q.s. to 100%

1. Tetanus toxoid adsorbed comprises approximately 0.0004% (by mass) purified tetanus toxoid (a permanently inactivated form of tetanus toxin) adsorbed to a gel/precipitate of aluminum (n-hydroxy) phosphate in a sterile saline solution (sodium chloride) buffered with acetate. There is approximately 1 mg/mL aluminum
2. Diphtheria toxoid adsorbed comprises approximately 0.0004% (by mass) purified diphtheria toxoid (a permanently inactivated form of diphtheria toxin) adsorbed to a gel/precipitate of aluminum (n-hydroxy) phosphate in a sterile saline solution (sodium chloride) buffered with acetate. There is approximately 1 mg/mL aluminum

Note: Ingredients below reportable levels are not further specified.

4. FIRST AID MEASURES

First aid measures Eye contact	In case of eye contact, immediately flush eyes with fresh water for at least 5 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
Skin Contact	In case of contact, remove contaminated clothing. Flush skin with copious amounts of water for at least 5 minutes. Obtain medical attention if skin reaction occurs.
Inhalation	In case of inhalation, remove to fresh air.. If breathing is difficult seek medical attention immediately
Ingestion	In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention if needed. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
Self-protection of the first aider	This product presents no substantive risk to the first aider.

Most important symptoms and effects, both acute and delayed

symptoms Common effects of the vaccine include: pain, redness, or swelling of the injection site; fever; headache; muscle weakness; malaise; joint pain.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically, utilize information provided in the prescribing information / product insert supplied with the product.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding

environment.

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical
Not available.

Hazardous combustion products Not available.

Explosion data

Sensitivity to Mechanical Impact None

Sensitivity to Static Discharge None

Protective equipment and precautions for firefighters

Firefighter should use standard/approved breathing apparatus and protective gear as prescribed by local regulations and training.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Wear appropriate personal protective equipment (see Section 8).

Environmental precautions No special environmental precautions are required.

Environmental precautions See Section 12 for additional ecological information.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage when safe to do so.

Methods for cleaning up Wipe with absorbent material (e.g. cloth) for disposal. Area where spill occurred can be cleaned with the regular cleaning materials designated for the area.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store at 2° to 8°C (35° to 46°F). Protect from Freezing. Freezing the product or storing it under warmer conditions for an extended period presents no safety hazard to the handler but may impact the efficacy of the vaccine and thus can cause a safety hazard to patients.

Incompatible materials None Known

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

This product, as supplied, does not contain any hazardous materials with Occupational Exposure Limits (OEL) established by the region specific regulatory bodies.

Appropriate engineering controls

No special engineering controls are required to assure safety for handlers.

Engineering Controls

Used as supplied, clinicians (doctors and nurses) should use personal protective equipment and procedures appropriate to administering an injection. Gloves should be worn when administering the injection and stopping any bleeding at the injection site. Needles used for injections should be handled with care, not recapped after use and disposed of in an approved sharps container, following local regulations.

Individual protection measures, such as personal protective equipment

Eye/face protection

In laboratory or industrial settings, safety glasses with side shields are recommended.

Skin and body protection In laboratory or industrial settings, gloves and lab coats are recommended.

Respiratory protection

Used as supplied, general room ventilation is acceptable and no special respiratory protection is needed when administering the vaccine.

General Hygiene

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state

Liquid

Appearance

Cloudy or milky suspension.

Color

White, may appear slightly tan color off-white.

Odor

Not available

Odor threshold

Not available

Property

Values

Remarks/Method

pH

6.5-7.5

Melting point

Not Available

Freezing point

-1° to -20° Celsius

Boiling point / boiling range

approximately 100 ° Celsius

Flash point

Not Available

Evaporation rate

Not available

Flammability (solid, gas)

Not available.

Flammability Limit in Air

Upper flammability limit:

Not available.

Lower flammability limit:

Not available.

Vapor pressure

Not available.

Vapor density

Not available

Specific Gravity

Not available

Water solubility	Completely soluble if mildly acidified.
Solubility in other solvents	Not available.
Partition coefficient	Not available.
Autoignition temperature	Not available.
Decomposition temperature	Not available.
Kinematic viscosity	Not available.
Dynamic viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.
<u>Other Information</u>	
Softening point	Not available.
Molecular weight	Not available.
VOC Content (%)	Not available.
Density	Not available.
Bulk density	Not available.

10. STABILITY AND REACTIVITY

Reactivity

Not reactive under normal conditions.

Chemical stability

Stable under normal conditions.

Possibility of Hazardous Reactions

None under normal handling.

Hazardous polymerization Hazardous polymerization does not occur.

Conditions to avoid

Not available.

Incompatible materials

Not available.

Hazardous Decomposition Products

None under normal use conditions.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information	No data available.
Inhalation	No impact known or expected under normal use.
Eye contact	No impact known or expected under normal use.
Skin Contact	No impact known or expected under normal use.
Ingestion	No impact known or expected under normal use.

Information on toxicological effects

Symptoms Common effects of the vaccine when injected in accordance with the prescribing information include: pain, redness, or

swelling of the injection site; fever; headache; muscle weakness; malaise; joint pain.

Animal Data

Both the active ingredients Tetanus Toxoid and Diphtheria Toxoid are extensively tested in animals to demonstrate safety. Doses of 5 mg protein/Kg of each toxoid administered separately produce no observed adverse effect in Guinea Pigs. The toxoid proteins are each present in product at approximately 0.0002% by mass. In addition the final product is tested by the General Safety Test (formerly specified as 21 CFR 610.11) in mice and guinea pigs by injection at 25,000 mg/Kg (product) with no observed adverse events over 7 days.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	Not available.
Serious eye damage/eye irritation	Not available.
Sensitization	Not available
Germ cell mutagenicity	Not available
Carcinogenicity	Not available
Reproductive toxicity	Pregnancy C: Animal reproduction studies have not been conducted with Tetanus and Diphtheria Toxoids Adsorbed. However the World Health Organization (WHO) recommends vaccination with a tetanus toxoid containing vaccine for pregnant mothers where vaccination history is absent and incomplete. The US Centers for Disease Control and Prevention (CDC) recommend the use of similar vaccines (Tdap) in pregnant mothers at each pregnancy and has determined this to be safe.
Developmental Toxicity	Not available.
Teratogenicity	Not available.
STOT - single exposure	Not classified
STOT - repeated exposure	Not classified
Chronic toxicity	Not available
Subchronic toxicity	Not available
Target Organ Effects	Not available.
Neurological effects	Not available
Other adverse effects	Not available
Aspiration hazard	Not available

12. ECOLOGICAL INFORMATION

Ecotoxicity

Not available.

Persistence and degradability

Not available.

Bioaccumulation

Not available.

Mobility

Not available.

Other adverse effects Not available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes	Disposal should be in accordance with applicable regional, national and local laws and regulations. When working with local disposal regulations for land fill, incineration etc... it can be assumed that the liquid product contains approximately 0.15 ppm Hg (mercury) while the bulk product as packaged (product in glass vial with stopper, seal and cap) has been assayed at 0.21 ppm Hg (mercury)
Contaminated packaging	Disposal should be in accordance with applicable regional, national and local laws and regulations.

US EPA Waste Number Not applicable.

California Hazardous Waste Codes Not applicable.

14. TRANSPORT INFORMATION

DOT	Not regulated.
TDG	Not regulated.
MEX	Not regulated.
ICAO (air)	Not regulated.
IATA	Not regulated.
IMDG	Not regulated.
RID	Not regulated.
ADR	Not regulated.
ADN	Not regulated.

15. REGULATORY INFORMATION

US Federal Regulations SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute health hazard	No
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355).

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated by state right-to-know regulations.

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable.

16. OTHER INFORMATION

Revision Date October 20, 2015

Revision Note This document was redrafted in SDS format to replace the previous document (MassBiologics MSDS-23 Rev. 2) which was in now obsolete MSDS format. There were no changes in the composition of the product and no new data or information became available concerning the product.

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End of Safety Data Sheet