

# SAFETY DATA SHEET

United States



Version 1.0; December 31, 2019

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## Section 1. Product and Company Identification

**Product Name:** Kit for the Preparation of Technetium Tc 99m Mertiatide

**Catalogue Number:** N/A

### Grade: Pharmaceutical Reagent

**Tradenames and Synonyms:**

Kit for the Preparation of Technetium Tc 99m Mertiatide

**For active,** Betiatide,  
Mertiatide Kit

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**Recommended Use:** The content of this kit as sold is non radioactive. Kit for the Preparation of Technetium Tc 99m Mertiatide is a diagnostic radiopharmaceutical. It is supplied as a sterile, nonpyrogenic, lyophilized powder. After reconstitution with sterile sodium pertechnetate Tc 99m injection, the content becomes radioactive and the technetium Tc 99m mertiatide (disodium[N-[N-[N-(mercaptoacetyl) glycy]glycy] glycinato (2-) - N,N',N'',S']oxotechnetate (2-)) which is formed is suitable for intravenous administration.

Technetium Tc 99m mertiatide is a renal imaging agent for use in the diagnosis of congenital and acquired abnormalities, renal failure, urinary tract obstruction, and calculi in adults and pediatric patients. (See Pediatric Use.) It is a diagnostic aid in providing renal function, split function, renal angiograms, and renogram curves for whole kidney and renal cortex.

**Restrictions for Use:** After reconstitution with Technetium Tc 99m, this material must be handled only by trained health care professionals qualified to handle radioactive material.

**Company Identification:**

**MANUFACTURER/DISTRIBUTOR:**

**Pharmalucence Inc.**

**29 Dunham Road**

**Billerica, MA 01821**

Phone : + 1-781-275-7120 / 1-800-221-7554

Fax: + 781.275.2634

Hours of operation: (8:30am - 5:00pm)

Web Site: [www.pharmalucence.com](http://www.pharmalucence.com)

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## Section 2. Hazards identification

**OSHA/HCS status:**

While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

**Classification of the substance or mixture:**

Does not present hazards within the GHS list of Physical Hazard Classes.

**Health Hazards For the kit non-reconstituted:**

Skin & Eyes Contact: Not established

Inhalation: Not established.

Ingestion: Not established.

**Label Elements:**

Symbol: Not applicable

Signal Word: Not applicable

**Precautions:**

Read the Package Insert prior to use.

Promptly remove any contamination from skin, eyes or clothing. Avoid all unnecessary exposure to the chemical substance.

**Eye contact:**

Not expected to be a health hazard.

**Skin contact:**

Not expected to be a health hazard.

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**Inhalation:** Not expected to be a health hazard.  
**Ingestion:** Not expected to be a health hazard.  
**Chronic exposure:** Not expected to be a health hazard.  
**Aggravation of pre-existing Conditions:** No information found.  
**Supplemental information:** This safety data sheet covers the content of the kit as sold (non radioactive) prior to reconstitution.

## Section 3. Composition/information on ingredients

**Substance/mixture:** Mixture.  
**Other means of identification:** Not available.

**Composition:**

| Chemical Ingredients<br>Component (quantity per vial): | CAS #       | Wt % |
|--------------------------------------------------------|-------------|------|
| SODIUM TARTRATE                                        | 868-18-8    | 65.4 |
| LACTOSE                                                | 63-42-3     | 32.7 |
| BETIATIDE                                              | 103725-47-9 | 1.6  |
| STANNOUS CHLORIDE                                      | 7772-99-8   | 0.2  |

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

## Section 4. First aid measures

**Description of necessary first aid measures**

**Eye contact:** Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention if irritation develops and persists.

**Inhalation:** Move to fresh air. Call a physician if symptoms develop or persist.

**Skin contact:** Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

**Ingestion:** Rinse mouth. Get medical attention if symptoms occur. Never give anything by mouth to a victim who is unconscious or is having convulsions.

**Most important symptoms/effects, acute and delayed:** May cause an allergic skin reaction. Dermatitis. Rash  
The following adverse reactions have been reported: nausea, vomiting, wheezing, dyspnea, itching, rash, tachycardia, hypertension, shaking chills, fever, and seizure.

**Indication of immediate medical attention treatment needed, if necessary:** Provide general supportive measures and treat symptomatically.  
Keep victim under observation. Symptoms may be delayed

See toxicological information (Section 11)

## Section 5. Fire-fighting measures

**Extinguishing media**

**Suitable extinguishing media:** Use an extinguishing agent suitable for the surrounding fire.

**Specific hazards arising from the chemical:** In a fire or if heated, a pressure increase will occur and the container may burst.

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**Special protective actions for fire- fighters:** Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

**Special protective equipment for fire-fighters:** Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

## Section 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

**For Mertiatide before reconstitution:** To collect non-radioactive spills, use HEPA filtered vacuum or wet mop. Do not generate dust. Dispose of material as non-hazardous waste.

**For Mertiatide Reconstituted with Sodium Pertechnetate Tc-99m:** If any loss or release of the radioactive contents occurs, notify your Radiation Safety Officer. All cleanup operations should be performed according to the Standard Operating Procedures (SOP) for radiation protection established for your facility and by the NRC, or other applicable local, provincial, state or federal regulations.

## Section 7. Handling and storage

### Precautions for safe handling

**Protective measures:** Put on appropriate personal protective equipment (see Section 8).

**Advice on general occupational hygiene:** Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

**Conditions for safe storage, including any incompatibilities:** Keep container in a dark place. Do not store or consume food, drink or tobacco in areas where they may become contaminated with this material. Store at controlled room temperature 20-25°C (68-77°F).

**For Mertiatide reconstituted with Sodium Pertechnetate Tc-99m:** The shielded vial should be stored at or below room temperature but do not freeze. Refer to the package insert for specific approved storage temperatures after reconstitution. Handling devices such as syringe shields and tongs should be used. Storage and disposal of the reconstituted, radioactive product should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorised to license the use of this radionuclide.

## Section 8. Exposure controls/personal protection

### Control Parameters

#### **For Tin Compounds:**

| Airborne Exposure Limits                    | OSHA Permissible Exposure Limit (PEL) | ACGIH® Threshold Limit Value (TLV®) |
|---------------------------------------------|---------------------------------------|-------------------------------------|
| Stannous Chloride Dihydrate (CAS 7772-99-8) | 2 mg/m <sup>3</sup> (TWA), as Sn      | 2 mg/m <sup>3</sup> (TWA), as Sn    |

TWA = Time Weighted Average

**For Tc-99m:** NRC occupational concentration limit is 6 x 10E-3 µCi/mL of air.

**Appropriate engineering controls:** Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

**Environmental exposure controls:** Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

### Individual protection measures

**Eye/face protection:** Safety glasses with side-shields.

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**Skin protection:** Wear protective gloves and clean body-covering clothing.  
**Respiratory protection:** Not expected to require personal respirator usage.

## Section 9. Physical and chemical properties

### Appearance

|                                                     |                                   |
|-----------------------------------------------------|-----------------------------------|
| <b>Physical state:</b>                              | Lyophilized solid.                |
| <b>Color:</b>                                       | White.                            |
| <b>Odor:</b>                                        | Odorless.                         |
| <b>Odor threshold:</b>                              | Not available.                    |
| <b>pH:</b>                                          | Not available.                    |
| <b>Melting point:</b>                               | ca. 0 °C (32 °F) reconstituted    |
| <b>Boiling point:</b>                               | ca. 100 °C (212 °F) reconstituted |
| <b>Flash point:</b>                                 | Not applicable.                   |
| <b>Burning time:</b>                                | Not applicable.                   |
| <b>Burning rate:</b>                                | Not applicable.                   |
| <b>Evaporation rate:</b>                            | Not available.                    |
| <b>Flammability (solid, gas):</b>                   | Not available.                    |
| <b>Lower and upper explosive(flammable) limits:</b> | Not available.                    |
| <b>Vapor pressure:</b>                              | Not available.                    |
| <b>Vapor density:</b>                               | Not available.                    |
| <b>Relative density:</b>                            | Not available.                    |
| <b>Solubility:</b>                                  | Soluble                           |
| <b>Solubility in water:</b>                         | Soluble                           |
| <b>Auto-ignition temperature:</b>                   | Not available.                    |
| <b>Decomposition temperature:</b>                   | Not available.                    |
| <b>Viscosity:</b>                                   | Not available.                    |

## Section 10. Stability and reactivity

|                                            |                                                                                                      |
|--------------------------------------------|------------------------------------------------------------------------------------------------------|
| <b>Reactivity:</b>                         | The product is stable and non-reactive under normal conditions of use, storage and transport.        |
| <b>Chemical stability:</b>                 | The product is stable.                                                                               |
| <b>Possibility of hazardous reactions:</b> | Will not occur.                                                                                      |
| <b>Conditions to avoid:</b>                | No specific data.                                                                                    |
| <b>Incompatible materials:</b>             | No specific data.                                                                                    |
| <b>Hazardous decomposition products:</b>   | Under normal conditions of storage and use, hazardous decomposition products should not be produced. |

## Section 11. Toxicological information

The product is contained within an hermetically sealed glass serum vial and direct exposure is not likely to occur under normal handling and using the precautions described. Unusual events may lead to exposure through skin or eye contact. The information below pertains to the individual ingredients found in this product.

LACTOSE (CAS 63-42-3)  
**Acute Oral** LD50 Rat > 10000 mg/kg

STANNOUS CHLORIDE (CAS 7772-99-8)  
**Acute Oral** LD50 Mouse 1200 mg/kg

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Rat 700 mg/kg

|                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                        |
|------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Skin corrosion/irritation:</b>                                      | Prolonged skin contact may cause temporary irritation.                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Serious eye damage/eye irritation:</b>                              | Direct contact with eyes may cause temporary irritation.                                                                                                                                                                                                                                                                                                                                                               |
| <b>Respiratory or skin sensitization:</b>                              |                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Respiratory sensitization:</b>                                      | Not available.                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Skin sensitization:</b>                                             | May cause an allergic skin reaction.                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Germ cell mutagenicity</b>                                          | For the content of kit as sold prior to reconstitution (non radioactive): No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.                                                                                                                                                                                                                             |
| <b>Carcinogenicity:</b>                                                | For the content of kit as sold prior to reconstitution (non radioactive): This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.                                                                                                                                                                                                                                                              |
| <b>IARC Monographs. Overall Evaluation of Carcinogenicity:</b>         | Not listed.                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>NTP Report on Carcinogens:</b>                                      | Not listed.                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053):</b> | Not regulated.                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Reproductive toxicity</b>                                           | For the content of kit as sold prior to reconstitution (non radioactive): Due to lack of data the classification is not possible. For Kit for the Preparation of Technetium Tc 99m Mertiotide Reconstituted with Sodium Pertechnetate Tc-99m: May cause harm to breastfed babies. Technetium Tc-99m is excreted in human milk during lactation, therefore, formula-feedings should be substituted for breast-feedings. |
| <b>Specific target organ toxicity - single exposure:</b>               | Due to partial or complete lack of data the classification is not possible.                                                                                                                                                                                                                                                                                                                                            |
| <b>Specific target organ toxicity - repeated exposure:</b>             | Due to partial or complete lack of data the classification is not possible.                                                                                                                                                                                                                                                                                                                                            |
| <b>Aspiration hazard:</b>                                              | Due to partial or complete lack of data the classification is not possible.                                                                                                                                                                                                                                                                                                                                            |
| <b>Chronic effects:</b>                                                | For the content of kit as sold prior to reconstitution (non radioactive): Prolonged inhalation may be harmful.                                                                                                                                                                                                                                                                                                         |

## Section 12. Ecological information

|                                                |                                                   |
|------------------------------------------------|---------------------------------------------------|
| <b>Toxicity:</b>                               | Not available.                                    |
| <b>Persistence and degradability:</b>          | Not available.                                    |
| <b>Bioaccumulative potential:</b>              | Not available.                                    |
| <b>Mobility in soil:</b>                       | Not available.                                    |
| <b>Soil/water partition coefficient (KOC):</b> | Not available.                                    |
| <b>Other adverse effects:</b>                  | No known significant effects or critical hazards. |

## Section 13. Disposal considerations

|                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Disposal methods:</b> | <p>The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.</p> <p>If reconstituted with Technetium Tc-99m, notify your site Radiation Safety Officer and follow spill control and waste management procedures for radioactive material spills in the Technelite MSDS.</p> |
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## Section 14. Transport information

Product is not regulated as dangerous goods for transport.

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## Section 15. Regulatory information

U.S. Federal regulations:

Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs):

Not listed.

Clean Air Act Section 602 Class I Substances:

Not listed.

Clean Air Act Section 602 Class II Substances:

Not listed.

DEA List I Chemicals (Precursor Chemicals):

Not listed.

DEA List II Chemicals (Essential Chemicals):

Not listed.

SARA 302/304

Composition/information on ingredients:

No products were found.

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## Section 16. Other information

Issue Date: 12-31-2019

Revision Date: -

Version #: 01

This document pertains, in most part, to the non-radioactive, non-reconstituted, lyophilized product. Once reconstituted with radioactive <sup>99m</sup>Tc, the material falls under the regulation of the MRCPP, NRC, or other local, provincial, state, or federal agencies. Only trained professionals in licensed facilities are permitted to handle the radioactive reconstituted product.

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**DISCLAIMER:** This above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Pharmalucence shall not be held liable for any damage resulting from handling or from contact with the above material.