



## Material Safety Data Sheet

### Kit for the preparation of Technetium Tc 99m Penetate Injection Diagnostic for Intravenous Use

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#### CHEMICAL PRODUCT/COMPANY IDENTIFICATION

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##### Material Identification

Grade: Pharmaceutical Drug (NDC # 45567-0010-1)

##### Trade names and Synonyms

Kit for the Preparation of Technetium Tc 99m Pentetate Injection Diagnostic for Intravenous Use; synonyms:

- (1) Calciate (3-), [N,N-bis[2-[bis(carboxymethyl)amino]ethyl]glycinato(5-)-], trisodium
- (2) (2) Trisodium [N,N-bis[2-[bis(carboxymethyl)amino]ethyl]glycinato(5-)-] calciate(3-).

##### Company Identification

#### MANUFACTURER/DISTRIBUTOR

**Pharmalucence, Inc.,**  
10 DeAngelo Drive  
Bedford, MA 01730

#### PHONE NUMBERS

Product Information: 1-800-221-7554  
Medical Emergency: 1-800-221-7554

#### COMPOSITION/INFORMATION ON INGREDIENTS

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##### Components

<u>Material</u>	<u>CAS Number</u>	<u>%</u>
STANNOUS CHLORIDE, DIHYDRATE	7772-99-8	1.4
PENTETATE CALCIUM TRISODIUM	12111-24-9	98.6

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#### HAZARDS IDENTIFICATION

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##### Potential Health Effects

The only adverse effects associated with parenteral administration of Kit for the Preparation of Technetium Tc 99m Pentetate Injection Diagnostic for Intravenous Use have been Pyrogenic as well allergic reactions.

Toxicity information on the constituents of Kit for the Preparation of Technetium Tc 99m Pentetate Injection Diagnostic for Intravenous Use is summarized as follows:

#### STANNOUS CHLORIDE, DIHYDRATE

Material is extremely destructive to tissues of the mucous membranes and upper respiratory tract, eyes, and skin.

Inhalation may be fatal as a result of spasm, inflammation, and edema of the larynx and bronchi, chemical pneumonitis and pulmonary edema.

Symptoms of exposure may include burning sensation, coughing, wheezing, and laryngitis, shortness of breath, headache, nausea and vomiting.

#### PENTETATE CALCIUM TRISODIUM

May be harmful if inhaled. May cause respiratory tract irritation. May be harmful if absorbed through skin. May cause skin irritation. May cause eye irritation. May be harmful if swallowed.

#### Carcinogenicity Information

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

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### **FIRST AID MEASURES**

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#### INHALATION

Not expected to require first aid measures.

#### SKIN CONTACT

In case of contact, wash skin with soap and water. Call a physician. Wash contaminated clothing before reuse.

#### EYE CONTACT

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.

#### INGESTION

If swallowed, immediately give two glasses of water. Never give anything to an unconscious person. Call a physician.

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### **FIRE FIGHTING MEASURES**

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#### Flammable Properties

Not a fire or explosion hazard.

### Extinguishing Media

Water Spray, Foam, Dry Chemical, CO<sub>2</sub>.

### Fire Fighting Instructions

Evacuate personnel to a safe area. Keep personnel removed and upwind of fire. Wear self-contained breathing apparatus. Wear full protective equipment.

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## **ACCIDENTAL RELEASE MEASURES**

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### Safeguards (Personnel)

Wear Safety glasses and rubber gloves when handling.

### Spill Clean Up

Sweep up all possible for reclamation. Wash area with water.

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## **HANDLING AND STORAGE**

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### Handling (Personnel)

Avoid contact with eyes, skin, or clothing. Wash thoroughly after handling.

### Handling (Physical Aspects)

N/A

### Storage

Store at a controlled room temperature 15 – 30 °C.

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## **EXPOSURE CONTROLS/PERSONAL PROTECTION**

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### Engineering Controls

Handle in a laboratory fume hood, or other suitably ventilated work area.

### Personal Protective Equipment

Wear safety glasses with side shields.

### Exposure Guidelines

N/A

### Applicable Exposure Limits

N/A

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## PHYSICAL AND CHEMICAL PROPERTIES

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### Physical Data

Solubility in Water: Soluble.  
Form: Lyophilized solid.

Kit for the Preparation of Technetium Tc 99m Pentetate Injection Diagnostic for Intravenous Use is supplied in a 10 ml serum vial. The contents of the vial are lyophilized and stored under nitrogen. See the product package insert for further information.

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## STABILITY AND REACTIVITY

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### Chemical Stability

Stable at normal temperatures and storage conditions.

### Incompatibility with Other Materials

None reasonably foreseeable.

### Decomposition

Decomposition will not occur if handled and stored properly.

### Polymerization

Polymerization will not occur.

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## TOXICOLOGICAL INFORMATION

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### Animal Data

Information on the adverse effects of this material in animal studies by the inhalation, dermal, oral, or ocular route(s) of exposure is not available. Information for the constituent materials is summarized as follows:

#### STANNOUS CHLORIDE, DIHYDRATE

##### Intravenous Data

LD50: 700 mg/kg (rat)

#### PENTETATE CALCIUM TRISODIUM

No data available

*LD50 is the median dose at which lethality occurred in 50% of the animals tested following oral or dermal exposure or exposure by injection.  
No evidence of carcinogenicity.*

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## **DISPOSAL CONSIDERATIONS**

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### Waste Disposal

Treatment, storage, transportation, and disposal must be in accordance with applicable Federal, State/Provincial, and Local regulations.

If reconstituted with Technetium Tc-99m, notify your site Radiation Safety Officer and follow waste management procedures for radioactive material.

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## **TRANSPORTATION INFORMATION**

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### Shipping Information

The known properties of this material, as packaged, do not constitute a hazard as defined by the U.S. Department of Transportation.

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## **OTHER INFORMATION**

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### NFPA, NPCA-HMIS

#### NFPA Rating

Health: 0  
Flammability: 0  
Reactivity: 0

#### NPCA-HMIS Rating

Health: 0  
Flammability: 0  
Reactivity: 0

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The data in this Material Safety Data Sheet relates only to the specific material designated herein and does not relate to use in combination with any other material or in any process.

End of MSDS