



Material Safety Data Sheet

Kit for the Preparation of Technetium Tc 99m Sulfur Colloid Injection Diagnostic for Intravenous and Oral Use

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CHEMICAL PRODUCT/COMPANY IDENTIFICATION

Material Identification

Grade: Pharmaceutical Drug (NDC 45567-0030-1)

Trade names and Synonyms

Kit for the Preparation of Technetium Tc 99m Sulfur Colloid Injection Diagnostic for Intravenous and Oral Use

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

Components

<u>Material</u>	<u>CAS Number</u>	<u>%</u>
Sodium Thiosulfate Anhydrous	7772-98-7	9
Edetate disodium (EDTA)	6381-92-6	10
Gelatin	9000-70-8	81

HAZARDS IDENTIFICATION

Potential Health Effects

Although rare, deaths have occurred following intravenously administered gelatin stabilized Technetium Tc 99m Sulfur Colloid injection, advanced cardiopulmonary life support systems should be readily available where and when the drug is administered.

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

Sodium Thiosulfate Anhydrous

Inhalation:

May cause irritation to the respiratory tract. Symptoms may include coughing and shortness of breath.

Ingestion:

Low level of toxicity by ingestion. Diarrhea may occur by ingestion of large quantities.

Skin Contact:

Irritation may occur from prolonged contact.

Edetate disodium

Inhalation:

May cause irritation to the respiratory tract.

Ingestion:

Low level of toxicity by ingestion.

Skin Contact:

Irritation may occur from prolonged contact.

Gelatin

Inhalation:

May cause irritation to the respiratory tract.

Ingestion:

May be harmful if swallowed.

Skin Contact:

Irritation may occur from prolonged contact.

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.

FIRST AID MEASURES

INHALATION

Not expected to require first aid measures.

SKIN CONTACT

In case of contact, wash skin with soap and water. 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.

FIRE FIGHTING MEASURES

Flammable Properties

Not expected to be a fire or explosion hazard.

Extinguishing Media

Water Spray, Foam, Dry Chemical, CO₂.

Fire Fighting Instructions

Evacuate personnel to a safe area. Keep personnel removed and upwind of fire.

ACCIDENTAL RELEASE MEASURES

Safeguards (Personnel)

Wear Safety glasses and rubber gloves when handling.

Spill Clean Up

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

HANDLING AND STORAGE

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.

EXPOSURE CONTROLS/PERSONAL PROTECTION

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

PHYSICAL AND CHEMICAL PROPERTIES

Physical Data

Solubility in Water: Soluble.
Form: Lyophilized solid.

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

STABILITY AND REACTIVITY

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.

TOXICOLOGICAL INFORMATION

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.

DISPOSAL CONSIDERATIONS

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.

TRANSPORTATION INFORMATION

Shipping Information

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

OTHER INFORMATION

NFPA, NPCA-HMIS**NFPA Rating**

Health: 0
Flammability: 0
Reactivity: 0

NPCA-HMIS Rating

Health: 0
Flammability: 0
Reactivity: 0

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