



Material Safety Data Sheet

Sestamibi ®

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CHEMICAL PRODUCT/COMPANY IDENTIFICATION

Material Identification

Grade: Pharmaceutical Drug

Tradenames and Synonyms

Kit for the Preparation of Technetium Tc 99m Sestamibi Injection.
Drug substance: Tetrakis (2-methoxy isobutyl isonitrile) copper (I) tetrafluoroborate (Cu-MIBI) and stannous (II) chloride

Company Identification

MANUFACTURER/DISTRIBUTOR

Pharmalucence, Inc.
29 Dunham Road
Billerica, MA 01821

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>
Tetrakis (2-methoxy isobutyl isonitrile) copper (I) tetrafluoroborate	103694-84-4	4.1%
Hazardous: no		
Sodium citrate dihydrate	6132-04-3	10.5%
Hazardous: no		
Mannitol	69-65-8	81.1%
Hazardous: no		
L-cysteine hydrochloride monohydrate	7048-04-6	4.1%
Hazardous: yes – irritant		
Stannous chloride dihydrate	10025-69-1	0.3%
Hazardous: yes – harmful if swallowed, causes burns. PEL 8H TWA 2 MG(SN)/M		

HAZARDS IDENTIFICATION

Potential Health Effects

Eye Contact:

May cause irritation.

Skin Contact:

Exposure may occur via skin contact if gloves and protective clothing are not worn. The extent of systemic absorption of the material after skin contact is not known.

Toxic:

Contact with small quantities of material for short periods is not expected to result in pharmacologic or toxic effects.

Irritation:

Material contains components that are irritants. It may have potential to cause mild irritation; however, moderate or severe irritation is not expected.

Inhalation:

Under normal conditions, this material is handled in closed vials and exposure by inhalation is not expected to occur.

Acute:

Formulation contains some materials that are irritants. Inhaling small amounts of dust may result in irritation.

Ingestion:

Ingestion of large quantities of this material in an occupational setting would not be expected to occur. Ingestion of trace amounts of the material might occur if the material contacts hands and hands are not washed prior to eating, drinking or smoking. The extent of systemic absorption after ingestion is not known.

Acute:

Inadvertent ingestion of trace amounts of this material would not be expected to result in symptoms.

Chronic Health Effects:

Repeated and prolonged exposure to skin may cause skin irritation.

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

Remove exposed person to fresh air. If person is not breathing, give artificial respiration. If breathing is difficult administer oxygen. Get medical attention immediately.

SKIN CONTACT

Remove contaminated clothing. Wash skin with plenty of water for 5 minutes. Seek medical attention if irritation (redness, itching or swelling) develops or persists.

EYE CONTACT

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

INGESTION

Get medical attention immediately. Vomiting may be induced if a person is conscious and if ingestion has occurred within the past three hours. Never induce vomiting in a person who is unconscious or experiencing convulsions.

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

Firefighters should wear self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves. Evacuate personnel to an upwind direction; remove unneeded material and cool container(s) with water from a maximum distance.

ACCIDENTAL RELEASE MEASURES

Safeguards (Personnel)

Lab coat, impermeable gloves (latex, latex/nitrile or nitrile) and eye protection should be worn as a minimum precaution. Sweep material onto paper and place into a fiber drum for reclamation or disposal. The spill area should be ventilated and decontaminated after material has been picked up. Spill Clean Up: use HEPA filtered vacuum or wet mop. Do not generate dust

HANDLING AND STORAGE

Handling (Personnel)

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

Handling (Physical Aspects)

Avoid generation of dust.

Storage

Do not store or consume food, drink or tobacco in areas where they may become contaminated with this material. Store between 20 – 25 °C (68 – 77 °F).

EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls

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

Personal Protective Equipment

Wear safety glasses (ANSI Z87.1) as well as impermeable gloves (latex, latex/nitrile or nitrile).

Exposure Guidelines

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 Sestamibi Injection is supplied in a 10 ml vial. The contents of the vial are lyophilized and stored under nitrogen. 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

Applies to All Ingredients:

Acute Health Effects:

Intravenous data: (rat)	LD50: 8 mg/kg	LD50: 10 mg/kg (dog) LD50: 12 mg/kg (mouse) LDLo: 7 mg/kg (rat)
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Ingestion effects: LD50: 80 mg/kg
(mouse) LD50: 123
mg/kg (rat)

Mutagenicity: tetrafluoroborate was not genotoxic in an "*in vitro*" Ames, Chinese Hamster Ovary sister chromatid exchange, and "*in vivo*" mouse micronucleus assays. It did cause chromosomal aberrations in an "*in vitro*" human lymphocyte assay at cytotoxic concentrations.

Other toxicological information:
Ocular data: Mild eye irritant in animals.

Clinical signs of overdose in mice were dyspepsia, diarrhea, hypoactivity, hypothermia, anorexia, ataxia, and tremors.

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: 2
Flammability: 0
Reactivity: 0

NPCA-HMIS Rating

Health: 2
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