

SAFETY DATA SHEET

1. Identification

Product identifier	KIT FOR THE PREPARATION OF TECHNETIUM Tc99m SESTAMIBI INJECTION
Other means of identification	
SDS number	MHSMB
Synonyms	Sestamibi imaging agent.
Recommended use	The content of this kit as sold is non radioactive. Kit for Intravenous use only. Technetium Tc 99m Sestamibi, is a myocardial perfusion agent indicated for detecting coronary artery disease by localizing myocardial ischemia (reversible defects) and infarction (non-reversible defects) as well as evaluating myocardial function and developing information for use in patient management decisions.
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Supplier	
Company name	Curium US LLC
Address	2703 Wagner Place Maryland Heights, MO 63043 United States
Telephone number	Customer Service 888-744-1414
E-mail	NuclearMedicine@curiumpharma.com
Emergency telephone number:	24 Hour Emergency 314-595-3700 Chemtrec 800-424-9300

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Sensitization, skin	Category 1
OSHA defined hazards	Not classified.	

Label elements



Signal word	Warning
Hazard statement	May cause an allergic skin reaction.
Precautionary statement	
Prevention	Avoid breathing dust. Wear protective gloves. Contaminated work clothing must not be allowed out of the workplace.
Response	If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	This safety data sheet covers the content of the kit as sold (non radioactive) prior to reconstitution. Kit for Intravenous use only. Possible dust explosion hazard but because of the small quantity handled this classification does not apply.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
D-MANNITOL	69-65-8	80
SODIUM CITRATE	68-04-2	10
COPPER TETRAMIBI TETRAFLUOROBORATE	103694-84-4	5
L-CYSTEINE HYDROCHLORIDE	52-89-1	5
STANNOUS CHLORIDE DIHYDRATE	10025-69-1	< 1

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Kit for the Preparation of Technetium Tc 99m Sestamibi Injection is supplied as a 10 mL vial in a kit of five (5) (NDC # 69945-092-20) or a carton of thirty (30) (NDC # 69945-092-40), sterile and non-pyrogenic. Prior to lyophilization the pH is between 5.6-5.7. The contents of the vial are lyophilized and stored under nitrogen. Protect from light prior to reconstitution. Store at 15° to 25°C (59° to 77°F) before and after reconstitution.

4. First-aid measures

Inhalation

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

Skin contact

Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions.

Eye contact

Rinse with water. Get medical attention if irritation develops and persists.

Ingestion

Rinse mouth. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Dermatitis. Rash. May cause an allergic skin reaction. Technetium Tc 99m Sestamibi has been rarely associated with acute severe allergic and anaphylactic events of angioedema and generalized urticaria. In some patients the allergic symptoms developed on the second injection during Technetium Tc 99m Sestamibi imaging.

The following adverse reactions have been reported in > 0.5% of patients: signs and symptoms consistent with seizure occurring shortly after administration of the agent; transient arthritis; angioedema, arrhythmia, dizziness, syncope, abdominal pain, vomiting, and severe hypersensitivity characterized by dyspnea, hypotension, bradycardia, asthenia, and vomiting within two hours after a second injection of Technetium Tc 99m Sestamibi. A few cases of flushing, edema, injection site inflammation, dry mouth, fever, pruritis, rash, urticaria and fatigue have also been attributed to administration of the agent.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

General information

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media

Water. Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

Unsuitable extinguishing media

Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical

As with most organic solids, fire is possible at elevated temperatures or by contact with an ignition source. Mannitol: Minimum explosible concentration = 0.065 g/l; Maximum explosion pressure: 97 lb/sq. in., Mannitol: Flash Point: > 149C (300F) Minimum dust cloud ignition temperature: 460C (860F). During fire, hazardous combustion products are released that may include: Carbon oxides (CO_x). Metal oxides. Halogenated compounds.

Special protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions

In case of fire do not breath fumes. Use water spray to cool unopened containers.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards Dust may form explosive mixture with air.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Wear appropriate personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid dust formation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Stop the flow of material, if this is without risk. Collect in containers and seal securely. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Do not get in eyes, on skin, or on clothing. Avoid generation and spreading of dust. When using, do not eat, drink or smoke. Protect from light. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Use care in handling/storage. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities Store at controlled room temperature 15-25°C. The contents of the vial are lyophilized and stored under nitrogen. Keep material from heat, light, and flame. Store locked up. Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

Storage and disposal of product should be controlled in a manner which is in compliance with the appropriate regulations of the federal or state government agency authorized to license the use of this radionuclide.

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
STANNOUS CHLORIDE DIHYDRATE (CAS 10025-69-1)	PEL	2 mg/m ³

US. ACGIH Threshold Limit Values

Components	Type	Value
STANNOUS CHLORIDE DIHYDRATE (CAS 10025-69-1)	TWA	2 mg/m ³

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
STANNOUS CHLORIDE DIHYDRATE (CAS 10025-69-1)	TWA	2 mg/m ³

Biological limit values No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn. Ventilation should be sufficient to effectively remove and prevent buildup of any dusts or fumes that may be generated during handling or thermal processing.

Individual protection measures, such as personal protective equipment

Eye/face protection If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Chemical resistant gloves. Suitable gloves can be recommended by the glove supplier.

Skin protection

Other Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended.

Respiratory protection No personal respiratory protective equipment normally required.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

When using, do not eat, drink or smoke. 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 to remove contaminants. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties**Appearance**

Physical state	Solid.
Form	Solid. Powder.
Color	White.

Odor Slight garlic-like odor.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Moderately soluble (1.0 - <10%)

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Explosive properties Not explosive.

Oxidizing properties Not oxidizing.

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Exposure to light. Heat, flames and sparks. Contact with incompatible materials.

Incompatible materials Strong oxidizing agents. Strong acids. Strong bases.

Hazardous decomposition products No hazardous decomposition products are known.

11. Toxicological information**Information on likely routes of exposure**

Inhalation May be harmful if inhaled. Large quantities of inhaled material could cause irritation of the upper respiratory tract. A tickling cough is a common symptom.

Skin contact May be harmful in contact with skin. May be irritating to the skin. May cause an allergic skin reaction.

Eye contact Direct contact with eyes may cause temporary irritation.

Ingestion May be harmful if swallowed. Swallowing may cause gastrointestinal irritation. Nausea. Diarrhea. Large doses produce vomiting, chills, dizziness, chest pain heart failure and pulmonary edema. Large doses may produce fluid and electrolyte imbalance, including circulatory overload and acidosis at high levels.

Symptoms related to the physical, chemical and toxicological characteristics Dermatitis. Rash. May cause an allergic skin reaction. Technetium Tc 99m Sestamibi has been rarely associated with acute severe allergic and anaphylactic events of angioedema and generalized urticaria. In some patients the allergic symptoms developed on the second injection during Technetium Tc 99m Sestamibi imaging.

The following adverse reactions have been reported in > 0.5% of patients: signs and symptoms consistent with seizure occurring shortly after administration of the agent; transient arthritis; angioedema, arrhythmia, dizziness, syncope, abdominal pain, vomiting, and severe hypersensitivity characterized by dyspnea, hypotension, bradycardia, asthenia, and vomiting within two hours after a second injection of Technetium Tc 99m Sestamibi. A few cases of flushing, edema, injection site inflammation, dry mouth, fever, pruritis, rash, urticaria and fatigue have also been attributed to administration of the agent.

Information on toxicological effects

Acute toxicity May cause an allergic skin reaction.

Components	Species	Test Results
STANNOUS CHLORIDE DIHYDRATE (CAS 10025-69-1)		
Acute		
Oral		
LD50	Mouse	1200 mg/kg
	Rabbit	10 g/kg
	Rat	700 mg/kg
Other		
LD100	Dog	159 mg/kg
	Mouse	66 mg/kg
LD50	Rat	52 mg/kg

Skin corrosion/irritation Due to partial or complete lack of data the classification is not possible.

Serious eye damage/eye irritation May cause eye irritation.

Respiratory or skin sensitization

Respiratory sensitization Due to partial or complete lack of data the classification is not possible.

Skin sensitization May cause an allergic skin reaction.

Germ cell mutagenicity 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.

The active intermediate, Cu(MIBI)4BF4, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/HPRT and sister chromatid exchange tests (all in vitro). At cytotoxic concentrations (>20 µg/mL), an increase in cells with chromosome aberrations was observed in the in vitro human lymphocyte assay. Cu(MIBI)4BF4 did not show genotoxic effects in the in vivo mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9 mg/kg, > 600 X. maximal human dose).

Carcinogenicity 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.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

NTP Report on Carcinogens

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

Reproductive toxicity Due to partial or complete lack of data the classification is not possible.

Specific target organ toxicity - single exposure Due to partial or complete lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure Due to partial or complete lack of data the classification is not possible.

Aspiration hazard Due to partial or complete lack of data the classification is not possible.

Chronic effects Prolonged inhalation may be harmful.

12. Ecological information

Ecotoxicity There are no data on the ecotoxicity of this product.

Components	Species	Test Results
STANNOUS CHLORIDE DIHYDRATE (CAS 10025-69-1)		
Aquatic		
Crustacea	EC50 Water flea (Daphnia magna)	55 mg/l, 48 hours

Persistence and degradability No data is available on the degradability of any ingredients in the mixture.

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

D-MANNITOL (CAS 69-65-8) -3.1

Mobility in soil No data available.

Other adverse effects An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

13. Disposal considerations

Disposal instructions For the content of kit as sold prior to reconstitution (non radioactive): Dispose in accordance with all applicable regulations. If medical waste is involved, such as blood, blood products, or sharps, the waste must be handled as a biohazard and disposed of accordingly. If not a biohazard, consult local, state and federal regulations for proper disposal.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations.

Contaminated packaging Dispose in accordance with all applicable regulations.

14. Transport information

DOT

UN number	UN2915
UN proper shipping name	Radioactive material, Type A package
Transport hazard class(es)	
Class	7
Subsidiary risk	8
Label(s)	7
Packing group	Not available.
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.
Special provisions	A56, W7, W8
Packaging exceptions	None
Packaging non bulk	415, 418, 419
Packaging bulk	415, 418, 419

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

Toxic Substances Control Act (TSCA) One or more components of the mixture are not on the TSCA 8(b) inventory or are designated "inactive".

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 302 Extremely hazardous substance**

Not listed.

SARA 311/312 Hazardous chemical Yes

Classified hazard categories Respiratory or skin sensitization

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations**US. Massachusetts RTK - Substance List**

STANNOUS CHLORIDE DIHYDRATE (CAS 10025-69-1)

US. New Jersey Worker and Community Right-to-Know Act

STANNOUS CHLORIDE DIHYDRATE (CAS 10025-69-1)

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

STANNOUS CHLORIDE DIHYDRATE (CAS 10025-69-1)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 18-February-2019

Revision date -

Version # 01

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