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 Canada Inc.

Address 2572 Daniel-Johnson Boulevard
Suites 217 & 220
Laval, QC H7T 2R3
Canada

Telephone number Customer Service phone number: 866-885-5988

E-mail NuclearMedicine@curiumpharma.com

Emergency telephone number: 24 Hour Emergency 314-595-3700

Chemtrec 800-424-9300

2. Hazard identification

Physical hazards Not classified.

Health hazards Sensitization, skin Category 1

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 should 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. Take off contaminated clothing and wash it before reuse.

Storage Store away from incompatible materials.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Other hazards 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	Common name and synonyms	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

During fire, hazardous combustion products are released that may include: Carbon oxides (COx). Metal oxides. Halogenated compounds.

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).

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. ACGIH Threshold Limit Values

Components	Type	Value
STANNOUS CHLORIDE DIHYDRATE (CAS 10025-69-1)	TWA	2 mg/m3

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value
STANNOUS CHLORIDE DIHYDRATE (CAS 10025-69-1)	TWA	2 mg/m3

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value
STANNOUS CHLORIDE DIHYDRATE (CAS 10025-69-1)	TWA	2 mg/m3

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

Components	Type	Value
STANNOUS CHLORIDE DIHYDRATE (CAS 10025-69-1)	TWA	2 mg/m3

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value
STANNOUS CHLORIDE DIHYDRATE (CAS 10025-69-1)	TWA	2 mg/m3

Canada. Quebec OELs. (Ministry of Labor - Regulation respecting occupational health and safety)

Components	Type	Value
STANNOUS CHLORIDE DIHYDRATE (CAS 10025-69-1)	TWA	2 mg/m3

Canada. Saskatchewan OELs (Occupational Health and Safety Regulations, 1996, Table 21)

Components	Type	Value
STANNOUS CHLORIDE DIHYDRATE (CAS 10025-69-1)	15 minute	4 mg/m3
	8 hour	2 mg/m3

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 OEL (occupational exposure limit), 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.

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.

Colour White.

Odour Slight garlic-like odor.

Odour 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.

Vapour pressure Not available.

Vapour 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.
Oxidising properties	Not oxidising.

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 oxidising 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. Diarrhoea. 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

Components	Species	Test Results
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 sensitisation

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

Skin sensitisation 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.

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

TDG

Not regulated as dangerous goods.

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

Canadian regulations This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Precursor Control Regulations

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto Protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

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
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

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