

MSDS Material Safety Data Sheet

From: Mallinckrodt Inc.
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24 Hour Emergency Telephone: 314-654-1600
CHEMTREC: 1-800-424-9300

National Response in Canada
CANUTEC: 613-996-6666

Outside U.S. and Canada
Chemtrec: 703-527-3887

NOTE: CHEMTREC, CANUTEC and National Response Center emergency numbers to be used only in the event of chemical emergencies involving a spill, leak, fire, exposure or accident involving chemicals.

KIT FOR THE PREPARATION OF TECHNETIUM Tc99m SESTAMIBI INJECTION

1. Product Identification

Synonyms: Sestamibi imaging agent
CAS No: Not applicable to mixtures.
Molecular Weight: Not applicable to mixtures.
Chemical Formula: Not applicable to mixtures.
Product Codes: N092

2. Composition/Information on Ingredients

Ingredient	CAS No.	Percent	Hazardous
D-Mannitol	69-65-8	80%	Yes
Sodium Citrate	68-04-2	10%	Yes
L-Cysteine Hydrochloride	52-89-1	5%	Yes
Copper tetramibi tetrafluoroborate	103694-84-4	5%	Yes
Stannous Chloride Dihydrate	10025-69-1	< 1%	No

3. Hazards Identification

Emergency Overview

CAUTION! MAY BE HARMFUL IF SWALLOWED OR INHALED. MAY CAUSE IRRITATION TO SKIN, EYES, AND RESPIRATORY TRACT. MAY FORM COMBUSTIBLE DUST CONCENTRATIONS IN AIR.

Potential Health Effects

Inhalation:

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

Ingestion:

May cause gastric irritation, nausea and 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.

Skin Contact:

May cause irritation and discoloration of sensitive skin areas. Possible irritation on prolonged contact with

moist or sensitive areas of the skin. Repeated skin contact may cause delayed hypersensitivity reactions in some individuals.

Eye Contact:

May cause irritation, redness and pain.

Chronic Exposure:

No information found.

Aggravation of Pre-existing Conditions:

No information found.

4. First Aid Measures

Inhalation:

Remove to fresh air. Get medical attention for any breathing difficulty.

Ingestion:

If large amounts were swallowed, give water to drink and get medical advice.

Skin Contact:

Wash exposed area with soap and water. Get medical advice if irritation develops.

Eye Contact:

Wash thoroughly with running water. Get medical advice if irritation develops.

5. Fire Fighting Measures

Fire:

As with most organic solids, fire is possible at elevated temperatures or by contact with an ignition source.

Mannitol: Flash Point: > 149°C (300°F)

Minimum dust cloud ignition temperature: 460°C (860°F)

Explosion:

Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Mannitol:

Minimum explosible concentration = 0.065 g/l;

Maximum explosion pressure: 97 lb/sq. in.

Fire Extinguishing Media:

Water spray, carbon dioxide, or dry powder.

Special Information:

In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode. Pressure from the extinguishing media may cause severe dusting.

6. Accidental Release Measures

Remove all sources of ignition. Ventilate area of leak or spill. Wear appropriate personal protective equipment as specified in Section 8. Spills: Clean up spills in a manner that does not disperse dust into the air. Use non-sparking tools and equipment. Reduce airborne dust and prevent scattering by moistening with water. Pick up spill for recovery or disposal and place in a closed container.

7. Handling and Storage

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage. Protect from light. Isolate from any source of heat or ignition. Store between 59-77°F Protect from freezing. Containers of this material may be hazardous when empty since they retain product residues (dust, solids); observe all warnings and precautions listed for the product.

8. Exposure Controls/Personal Protection

Airborne Exposure Limits:

- OSHA Permissible Exposure Limit (PEL):
1 mg/m³ (TWA) for copper dusts & mists as Cu
- ACGIH Threshold Limit Value (TLV):
1 mg/m³ (TWA) for copper dusts & mists as Cu

Ventilation System:

A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, "Industrial Ventilation, A Manual of Recommended Practices", most recent edition, for details.

Personal Respirator (NIOSH Approved)

If the exposure limit is exceeded and engineering controls are not feasible, a half facepiece particulate respirator (NIOSH type N95 or better filters) may be worn for up to ten times the exposure limit or the maximum use concentration specified by the appropriate regulatory agency or respirator supplier, whichever is lowest. A full-face piece particulate respirator (NIOSH type N100 filters) may be worn up to 50 times the exposure limit, or the maximum use concentration specified by the appropriate regulatory agency, or respirator supplier, whichever is lowest. If oil particles (e.g. lubricants, cutting fluids, glycerine, etc.) are present, use a NIOSH type R or P filter. For emergencies or instances where the exposure levels are not known, use a full-facepiece positive-pressure, air-supplied respirator. **WARNING:** Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.

Skin Protection:

Wear protective gloves and clean body-covering clothing.

Eye Protection:

Use chemical safety goggles. Maintain eye wash fountain and quick-drench facilities in work area.

9. Physical and Chemical Properties

Appearance:

White powder.

Odor:

Slight garlic like odor.

Solubility:

2-5 mg/mL water

Relative Density:

No information found.

pH:

No information found.

% Volatiles by volume @ 21°C (70°F):

No information found.

Boiling Point:

No information found.

Melting Point:

No information found.

Vapor Density (Air=1):

No information found.

Vapor Pressure (mm Hg):

No information found.

Evaporation Rate (BuAc=1):

No information found.

10. Stability and Reactivity

Stability:

Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products:

Carbon dioxide and carbon monoxide may form when heated to decomposition.

Hazardous Polymerization:

Will not occur.

Incompatibilities:

Strong oxidizing agents, strong acids, strong bases.

Conditions to Avoid:

Heat, flames, ignition sources and incompatibles.

11. Toxicological Information

Mannitol: Oral rat LD50: 13,500 mg/kg. Investigated as a tumorigen and mutagen.

Cancer Lists

Ingredient	---NTP Carcinogen---		IARC Category
	Known	Anticipated	
D-Mannitol (69-65-8)	No	No	None
Sodium Citrate (68-04-2)	No	No	None
L-Cysteine Hydrochloride (52-89-1)	No	No	None
Copper tetramibi tetrafluoroborate (103694-84-4)	No	No	None
Stannous Chloride Dihydrate (10025-69-1)	No	No	None

12. Ecological Information**Environmental Fate:**

No information found.

Environmental Toxicity:

No information found.

13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations.

Dispose of container and unused contents in accordance with federal, state and local requirements.

14. Transport Information

Not regulated.

15. Regulatory Information**Chemical Inventory Status**

Ingredient	TSCA	EC	Japan	Australia	Korea	---Canada---		
						DSL	NDSL	Phil.
D-Mannitol (69-65-8)	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
Sodium Citrate (68-04-2)	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
L-Cysteine Hydrochloride (52-89-1)	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
Copper tetramibi tetrafluoroborate (103694-84-4)	Exempt	No	No	No	No	No	No	No
Stannous Chloride Dihydrate (10025-69-1)	Exempt	No	Yes	Yes	No	No	No	Yes

Federal, State & International Regulations

Ingredient	---SARA 302---		-----SARA 313-----		CERCLA	-RCRA- 261.33	-TSCA- 8(d)
	RQ	TPQ	List	Chemical Catg.			
D-Mannitol (69-65-8)	No	No	No	No	No	No	No
Sodium Citrate (68-04-2)	No	No	No	No	No	No	No
L-Cysteine Hydrochloride (52-89-1)	No	No	No	No	No	No	No
Copper tetramibi tetrafluoroborate (103694-84-4)	No	No	No	No	No	No	No
Stannous Chloride Dihydrate (10025-69-1)	No	No	No	No	No	No	No

Chemical Weapons Convention: No TSCA 12(b): No CDTA: No
SARA 311/312: Acute: Yes Chronic: No Fire: Yes Pressure: No Reactivity: No (Mixture / Solid)
Australian Hazchem Code: None allocated. Australian Poison Schedule: None allocated.
WHMIS: This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

16. Other Information

NFPA Ratings:

Health: 1 Flammability: 1 Reactivity: 0

Label Hazard Warning:

CAUTION! MAY BE HARMFUL IF SWALLOWED OR INHALED. MAY CAUSE IRRITATION TO SKIN, EYES, AND RESPIRATORY TRACT. MAY FORM COMBUSTIBLE DUST CONCENTRATIONS IN AIR.

Label Precautions:

Avoid contact with eyes, skin and clothing.
Wash thoroughly after handling.
Avoid breathing dust.
Store in a tightly closed container.
Avoid dust cloud in presence of an ignition source.
Maintain adequate ventilation.

Label First Aid:

If swallowed, give several glasses of water to drink to dilute. If large amounts were swallowed or symptoms occur, get medical advice. Never give anything by mouth to an unconscious person. If inhaled, remove to fresh air. Get medical attention for any breathing difficulty. In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. Get medical attention if irritation develops or persists.

Product Use:

Diagnostic imaging agent

Revision Information:

MSDS Section(s) changed since last revision of document include: 1, 2, 3, 7, 10, 11.

Disclaimer:

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