

Material Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION	
<i>Product Information</i>	
Product Name	Cardiolite® (For The Preparation Of Technetium TC99m Sestamibi For Injection)
Version	2.2, 12/20/2006
Jurisdiction	This Material Safety Data Sheet was prepared for the jurisdiction USA.
Active substance	Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)
Synonyms	Tetrakis(2-Methoxyisobutylisonitrile)Copper(I) Tetrafluoroborate; Tc99m Sestamibi; Miraluma
Product Uses	This material is used as a medical imaging agent. It is combined with a radioactive material to form the solution for administration to the patient.
<i>Company/Undertaking Identification</i>	
Address	Lantheus Medical Imaging 331 Treble Cove Road Billerica, MA 01862 United States of America 1-800-299-3431
Emergency Phone Number	CHEMTREC 1-800-424-9300. For all international transportation emergencies call CHEMTREC at 1-703-527-3887. Collect calls accepted.

2. COMPOSITION/INFORMATION ON INGREDIENTS		
Components	Concentration	CAS-No.
<i>Hazardous components</i>		
Mannitol	80.97 %	69-65-8
<i>Other ingredients</i>		
Sodium Citrate Anhydrous	10.53 %	68-04-2
L-(+)-Cysteine hydrochloride, monohydrate	4.05 %	7048-04-6
Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)	4.05 %	103694-84-4
Stannous Chloride Dihydrate	0.40 %	10025-69-1
Other Information: Technetium-99m (Tc-99m) sestamibi is used as the radio pharmaceutical tracer. Technetium-99m (Tc-99m) is a gamma emitter with a maximum energy of 0.140 MeV. The physical half-life of Tc-99m is 6.02 hours.		

3. HAZARDS IDENTIFICATION	
<i>Emergency Overview</i>	
Appearance	solid : white, powder
Signal Word	Caution
Hazard Statements	May be harmful if ingested. May cause skin, eye and/or respiratory irritation. May cause allergic reaction. Target Organs: heart, bone marrow.

3. HAZARDS IDENTIFICATION

Precautionary Measures	Avoid ingestion, inhalation, skin and eye contact. Wash hands after handling to minimize exposure. Handle as a potentially hazardous material. The reconstituted product is radioactive. Care should be taken to minimize radiation exposure.
<i>Potential Health Effects</i>	
Eyes	May cause eye irritation.
Skin	May cause skin irritation.
Ingestion	May be harmful if swallowed.
Inhalation	May be harmful if inhaled.
Target Organs	heart, bone marrow
Signs and Symptoms	Acute: redness and swelling of skin and eyes, taste disturbance, nausea, gastrointestinal discomfort, headache, chest pain, loss of smell, Some of these effects occur after systemic exposure to diagnostic doses., It should be noted that some reported symptoms may be related to the disease process in the patient.
<i>Environmental Effects</i>	High mobility in soil Refer to Section 12

4. FIRST AID MEASURES

Eye Contact	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Obtain medical attention.
Skin Contact	Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.
Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. Obtain medical attention.
Ingestion	Obtain medical attention. Do NOT induce vomiting. Never give anything by mouth to an unconscious person.
Notes to Physician	This material is used as a medical imaging agent. It is combined with a radioactive material to form the solution for administration to the patient. This product can cause: redness and swelling of skin and eyes, taste disturbance, nausea, gastrointestinal discomfort, headache, chest pain, loss of smell, Some of these effects occur after systemic exposure to diagnostic doses., It should be noted that some reported symptoms may be related to the disease process in the patient., Organs effected may include: heart, bone marrow. Refer to Section 11. Pregnant or nursing women should avoid exposure.
Medical Surveillance	Employees, who are pregnant, are breast-feeding, or who are concerned with other reproductive issues should be encouraged to consult with the occupational health physician monitoring worker's health.

5. FIRE-FIGHTING MEASURES

Flammable Properties	Not available
Extinguishing Media	Suitable extinguishing media: Dry chemical, water spray, foam Unsuitable extinguishing media: Do NOT use water jet.

5. FIRE-FIGHTING MEASURES

Protection of Firefighters	<p>Specific hazards: Not available</p> <p>Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus.</p> <p>Hazardous Combustion Products: carbon oxides, nitrogen oxides (NO_x), sulphur oxides, sodium oxides, copper oxides, tin oxide fumes., gaseous hydrogen chloride (HCl)., gaseous hydrogen fluoride (HF)., hydrogen cyanide (hydrocyanic acid)</p>
Other Information:	Decontaminate protective clothing and equipment before reuse.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Refer to protective measures listed in sections 7 and 8. Use personal protective equipment. Examples include tightly fitting safety goggles, lab coat and impervious gloves. Wear respiratory protection. Depending on the nature of the spill (quantity and extent of spill) additional protective clothing and equipment such as a self-contained breathing apparatus may be needed. The reconstituted product is radioactive. Care should be taken to minimize radiation exposure.
Environmental Precautions	Prevent release to drains and waterways. Prevent release to the environment.
Containment Methods	Wet down any dusts to prevent generation of aerosols, if appropriate. Cover with suitable material.
Cleanup Methods	Spill prevention procedures and a spill response procedure should be implemented. Contain and collect spillage and place in container for disposal according to local regulations (see Section 13). Handle waste materials, including gloves, protective clothing, contaminated spill cleanup material, etc., as appropriate for chemically and pharmacologically similar materials. The reconstituted product is radioactive. Contact the company Radiation Safety Officer. Dispose of cleanup materials as radioactive waste. Isolate waste in sealed, clearly labeled containers and dispose of according to company procedures and governmental regulations.

7. HANDLING AND STORAGE

Handling Precautions	Avoid exposure - obtain special instructions before use. Avoid formation of dust and aerosols. Keep away from heat and sources of ignition. Prevent release to drains and waterways. The reconstituted product is radioactive. Contact the company Radiation Safety Officer. Label as radioactive material. Store and handle in a designated area. Use transfer pipets, spill trays and absorbent coverings to confine radioactive contamination. Obtain appropriate governmental licenses to possess and handle radioactive material.
Storage Conditions	Store at room temperature in the original container. Protect against light. Keep away from heat, sparks and flames. Store and handle in a designated area. Do not store near incompatible substances.
Container Requirements	Store in original container.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limit(s)	Company Guideline	ACGIH	OSHA	NIOSH
Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)	--	--	--	--
Stannous Chloride Dihydrate	--	0.2 mg/m3 STEL 0.1 mg/m3 TWA 2 mg/m3 TWA except tin hydride	0.1 mg/m3 TWA 2 mg/m3 TWA	25 mg/m3 IDLH except cyhexatin 0.1 mg/m3 TWA except cyhexatin 2 mg/m3 TWA except Tin oxide
Exposure Control Band	<u>Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)</u> 3 -- Material is assigned to Exposure Control Band 3 (range 20 - 50 µg/m3).			
Lantheus MI Exposure Guidelines Summary	<u>Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)</u> A specific exposure guideline has not yet been established. Materials require particular care and handling.			
Recommended Industrial Hygiene Monitoring Methods	A specific exposure sampling method is not available.			
Engineering Controls and Ventilation	Use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit. When handling quantities up to 25 grams, work in a standard laboratory using a fume hood, biological safety cabinet, glove box, or approved vented enclosure. When handling quantities up to 2 kilogram, work in a standard laboratory using a fume hood, biological safety cabinet, or approved vented balance safety enclosure. Quantities exceeding 2 kilogram should be handled in a designated laboratory using laminar flow/powder containment booth. For manufacturing and pilot plant operations, use direct coupling and closed transfer systems for all bulk transfers. Use dust tight valves as appropriate. HEPA filtration of local exhaust ventilation (LEV) is required.			

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory Protection	Use and selection of respiratory protection is based upon engineering controls in use and potential for aerosol generation. When engineering controls are not sufficient control exposure, wear an approved respirator with NIOSH Class 100 or high efficiency particulate (HEPA) filters or cartridges when exposures are up to ten times the exposure control guideline. Wear a loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator (PAPR) when exposures are 10-25 times the exposure control guideline. Wear a full facepiece negative pressure respirator with Class 100 or HEPA filters when exposures are 25-50 times the exposure control guideline. Wear a tight-fitting, full facepiece HEPA PAPR when exposures are 50-100 times the exposure control guideline. Wear a hood-shroud HEPA PAPR or full facepiece supplied air respirator operated in a pressure demand or other positive pressure mode when exposures are 100-1000 times the exposure control guideline. Note: May be harmful if inhaled.
Eye Protection	Safety glasses with side-shields are recommended. Face shields or chemical safety goggles may be required if splash potential exists or if corrosive materials are present. Note: Choice of eye protection may be influenced by the type of respirator which is selected.
Hand Protection	Impervious nitrile, rubber and latex gloves are recommended. If material is handled in solution, the solvent should also be considered when selecting protective clothing material. Please note that employees who are allergic to natural rubber latex should use nitrile gloves.
Skin and Body Protection	Wear a laboratory coat when handling quantities up to 2 kilograms. For quantities over 2 kilogram, wear laboratory coat or coverall of low permeability. For manufacturing operations, wear coverall of low permeability.
Hygiene	Wash hands and face before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES*Appearance*

Physical State	solid
Color	white
Form	powder

Descriptive properties

Molecular Weight	Not available
Molecular Formula	not applicable
Bulk Density	Not available
Evaporation Rate	Not available
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Log Octanol/Water Partition Coeff [log Kow]	Not available
Surface Tension	Not available
Odor	garlic-like odor
Odor Threshold	Not available
pH	5 - 6; (reconstituted)
pKa	Not available
Particle Size	Not available
Solubility, Water	25 g/l (soluble)

Continued

9. PHYSICAL AND CHEMICAL PROPERTIES

Specific Gravity/ Relative Density	Not available
Viscosity	Not available
<i>Thermal/Stability properties</i>	
Autoignition Temperature	Not available
Boiling Point	Not available
Thermal Decomposition	Not available
Explosive Limits, LEL	Not available
Explosive limits, LEL	Not available
Explosiveness	Not available
Flammability	Not available
Flash Point	Not available
Melting Point	Not available
Oxidizing Potential	Not available
<i>Vapor Properties</i>	
Vapor Density	Not available
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

10. STABILITY AND REACTIVITY

<i>Stability</i>	
Chemical Stability	Stable under normal conditions.
Conditions To Avoid	Not available
Incompatible Products	strong oxidizing agents
Hazardous Decomposition Products	Hazardous decomposition products formed under fire conditions.: carbon oxides, nitrogen oxides (NO _x), sulphur oxides, sodium oxides, copper oxides, tin oxide fumes., gaseous hydrogen chloride (HCl)., gaseous hydrogen fluoride (HF)., hydrogen cyanide (hydrocyanic acid)
Hazardous Reactions	None known.
<i>Sensitivity to static discharge/Dust exp.</i>	
Summary Statements	Although material has not been specifically tested, fine dust suspended in air in sufficient concentration and in the presence of an ignition source may pose a potential explosion hazard. Provide appropriate bonding and grounding protection to control static charge. Powder handling equipment such as dust collectors, dryers, and mills may require additional protective measures (e.g. explosion venting, inerting, etc.).

11. TOXICOLOGICAL INFORMATION

Routes of Entry	Ingestion, Inhalation, Eye Contact, Skin contact
Eye Irritation	<u>Mannitol</u> May cause eye irritation. <u>L-(+)-Cysteine hydrochloride, monohydrate</u> May cause eye irritation. <u>Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)</u> May cause eye irritation.

11. TOXICOLOGICAL INFORMATION

Skin Irritation	<u>Mannitol</u> May cause skin irritation. <u>L-(+)-Cysteine hydrochloride, monohydrate</u> May cause skin irritation. <u>Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)</u> May cause skin irritation.
Respiratory Irritation	<u>Mannitol</u> May cause irritation of respiratory tract. <u>L-(+)-Cysteine hydrochloride, monohydrate</u> May cause irritation of respiratory tract. <u>Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)</u> May cause irritation of respiratory tract.
Sensitization	Not available
Acute Toxicity Study	Acute Oral <u>L-(+)-Cysteine hydrochloride, monohydrate</u> LD50(rat): 1,890 mg/kg LD50(mouse): 1,660 mg/kg <u>Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)</u> LD50(rat): 123 mg/kg LD50(mouse): 80 mg/kg Acute toxicity (other routes of administration) <u>Sodium Citrate Anhydrous</u> LD50 (rat, Intraperitoneal): 1,548 mg/kg LD50 (mouse, Intraperitoneal): 1,364 mg/kg LD50 (mouse, intravenous): 170 mg/kg LD50 (rabbit, intravenous): 449 mg/kg <u>Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)</u> LDlo (rat, intravenous): 7 mg/kg
Repeated Dose Toxicity	Not available
Genetic Toxicity	<u>Mannitol</u> Mutagenicity Assessment Did not show mutagenic effects in animal experiments. <u>Sodium Citrate Anhydrous</u> in vitro Ames reverse-mutation assay -- negative Mutagenicity Assessment Several studies were conducted. Not mutagenic in AMES Test. <u>Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)</u> in vitro Chromosome aberration test in vitro -- positive CHO/HGPRT mammalian cell forward gene-mutation assay -- negative

Continued

11. TOXICOLOGICAL INFORMATION

Ames reverse-mutation assay -- negative

in vivo

Mutagenicity (micronucleus test) (mouse) -- negative

Mutagenicity Assessment

Several studies were conducted. Most studies produced negative results. This compound is considered to have low risk for induction of genetic toxicity.

Carcinogenicity

Mannitol**Carcinogenicity Assessment**

This material did not show carcinogenic potential in animal studies.

Carcinogenicity	ACGIH	OSHA	NTP	IARC
Mannitol	--	--	--	--
Sodium Citrate Anhydrous	--	--	--	--
L-(+)-Cysteine hydrochloride, monohydrate	--	--	--	--
Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)	--	--	--	--

Reproductive Toxicity Not available

Developmental Toxicity

Mannitol**Developmental Toxicity Assessment**

Several developmental studies were conducted. Did not show teratogenic effects in animal experiments.

Sodium Citrate Anhydrous**Developmental Toxicity Assessment**

Did not show teratogenic effects in animal experiments. (This result is from a study on a structurally-and/or pharmacologically-related substance.)

L-(+)-Cysteine hydrochloride, monohydrate**Developmental Toxicity Assessment**

Did not show teratogenic effects in animal experiments.

Human Experience

Experiences with Human ExposureMannitol

Intravenous injection therapeutic use - Symptoms: diarrhoea, gastrointestinal disturbance, headache, nausea, vomiting, chills, dizziness, Thirst, lethargy, confusion, chest pain, dehydration, agitation, disorientation, convulsions. Other effects include: congestive heart failure, lowered blood pressure., changes in metabolism, anaphylaxis, CNS depression, coma, increased intracranial pressure, other central nervous effects, hearing loss, kidney toxicity, Lung oedema, increased urine volume, hemorrhage, changes in clinical chemistry parameters, death.

11. TOXICOLOGICAL INFORMATION

Target Organs	<u>Mannitol</u> kidney, lungs, cardiovascular system, endocrine system, gastrointestinal tract, immune system, central nervous system, inner ear (hearing)
Symptoms	<u>Mannitol</u> See "Human Experience". <u>Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)</u> redness and swelling of skin and eyes, taste disturbance, nausea, gastrointestinal disturbance, headache, chest pain
Other Toxicity Information	Not available

12. ECOLOGICAL INFORMATION

Ecotoxicological Information (Aquatic)	
Acute Toxicity to Fish	
<u>Sodium Citrate Anhydrous</u> LC50 (Poecilia reticulata, 96 H) : 18,000 mg/l	
Acute Toxicity to Aquatic Invertebrates	
<u>Sodium Citrate Anhydrous</u> EC50 (Daphnia magna, 48 H) : 5,600 mg/l	
Toxicity to aquatic plants	
<u>Sodium Citrate Anhydrous</u> EC50 (Chlorella vulgaris, 96 H) : 1,800 - 3,200 mg/l	
Toxicity to microorganisms	
<u>Sodium Citrate Anhydrous</u> EC50 (Pseudomonas fluorescens, 8 H) : 1,800 - 3,200 mg/l	
Ecotoxicological Information (Terrestrial)	Not available
Chemical fate information	
<u>Mannitol</u> Koc () : 5 High mobility in soil	
Other Information High mobility in soil	

13. DISPOSAL CONSIDERATIONS

Advice On Disposal And Packaging	Disposal should be in accordance with applicable regional, national, and local laws and regulations. Local regulations may be more stringent than regional or national requirements. After use follow local procedures for radioactive waste.
Other Information	This information presented below only applies to the material as supplied. Disposal by incineration is recommended.

14. TRANSPORT INFORMATION

This material is not a dangerous good for the purpose of transportation.

15. REGULATORY INFORMATION**United States of America**

OSHA Hazard Classification	No OSHA Hazards.
313 Toxic Release Inventory. Listed Chemicals/Compounds	No components listed on the SARA 313 inventory.
TSCA Inventory	Not listed. Food, drug and cosmetic products are exempt from TSCA.

International**Canada**

WHMIS	Not Rated Caution - substance not yet fully tested.
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DSL/NDL	Not listed.
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Mexico

Mexico Classification	Health classification - Moderate Hazard - 2 - Substances that can cause serious or permanent harm under emergency conditions
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Europe

EINECS/ELINCS Number	Mannitol: 200-711-8 Sodium Citrate Anhydrous: 200-675-3
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Symbol(s)	Xi: Irritant
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R-phrases(s)	not applicable
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S-phrases(s)	S22: Do not breathe dust. S36/37/39: Wear suitable protective clothing, gloves and eye/face protection. S38: In case of insufficient ventilation, wear suitable respiratory equipment. S45: In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).
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16. OTHER INFORMATION**MSDS preparation information**

Prepared by	Environmental Health & Safety 1-978-671-8673
Prepared on	12/20/2006

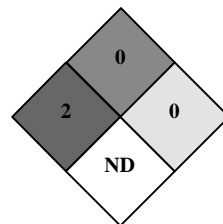
This Safety Data Sheet has been revised. This MSDS has been reformatted in a new electronic system. This data sheet contains changes from the previous version in section(s): All.

Other Information

HMIS	Health	2
	Flammability	0
	Reactivity	0
	Personal protective equipment	Not Determined (ND)

NFPA

Health	2
Fire	0
Reactivity	0
Special	ND



The information contained in this MSDS is believed to be accurate and represents the best information reasonably available at the time of preparation. However, we make no warranty, express or implied, with respect to such information. and we assume no liability from its use.