SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Cardiolite®

Version 3.1 11/4/2015

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.

COMPANY IDENTIFICATION: **Lantheus Medical Imaging**
331 Treble Cove Road
Billerica, MA 01862
United States of America
1-800-299-3431

EMERGENCY PHONE: **CHEMTREC 1-800-424-9300.**
For International Transportation Emergencies Call CHEMTREC @ 1-703-527-3887.
Collect Calls are accepted

SECTION 2: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:

Appearance White powder

Signal Word Caution

Hazard Statements May be harmful if ingested. May cuase skin, eye, and/or respiratory irritation. May cause allergic reaction. Traget Organs: Heart, Bone marrow

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.

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Potential Health Effects

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.
Environmental Effects	High mobility in soil. Refer to Section 12.

SECTION 3: COMPOSITION INFORMATION ON INGREDIENTS

Active Substance Copper (1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)

Common Name/Synonym: Tetrakis(2-Methoxyisobutylisonitrile)Copper(I) Tetrafluoroborate; Tc99m Sestamibi; Miraluma Tetrakis(2-Methoxyisobutylisonitrile) Copper(I) Tetrafluoroborate; Tc99m Sestamibi; Miraluma

Hazardous Components

Component	Concentration	CAS
Mannitol	80.97%	69-65-8

Other Components

Component	Concentration	CAS
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	0.4%	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.

SECTION 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	Remove contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. If skin irritation occurs, get medical advice/attention.
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.
Note to Physicians	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.

SECTION 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.
Protection of Firefighters	Specific hazards: Not available. Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus.

Hazardous Combustion Products	carbon oxides, nitrogen oxides (NOx), sulphur oxides, sodium oxides, copper oxides, tin oxide fumes., gaseous hydrogen chloride (HCl)., gaseous hydrogen fluoride (HF)., hydrogen cyanide (hydrocyanic acid).
Other Information	Decontaminate protective clothing and equipment before reuse

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precaution	Refer to protective measures listed in sections 7 and 8. Use personal protective equipment. Examples include tightly fitting safety goggles, lab coat or chemical protective suit 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. 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 material is radioactive. Contact the company Radiation 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.

SECTION 7: HANDLING AND STORAGE

Handling Precautions	Avoid exposure. Avoid formation of dust and aerosols. Keep away from heat and sources of ignition. Prevent release to drains and waterways*. For a complete discussion of Handling and Storage information, please consult the full prescribing information.* 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.
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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.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limit(s)	ACGIH	OSHA	NIOSH
Copper(1+), tetrakis[1-(isocyano-kC)-2- methoxy-2- methylpropane]-, (T- 4)-, tetrafluoroborate(1-)	---	---	---
Stannous Chloride Dihydrate	2mg/m^3 TWA except tin hydride	2 mg/m^3 TWA except tin hydride	100mg/m^3 IDLH as tin 2mg/m3 as tin except oxides

Exposure Control Band

Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T- 4)-,tetrafluoroborate(1-)

3 -- Material is assigned to Exposure Control Band 3 (range 20 - 50 µg/m^3).

Lantheus Medical Imaging Exposure Guidelines Summary

Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T- 4)-, tetrafluoroborate(1-)

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.

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
Follow good chemical hygiene practices. Wash hands and face before breaks and immediately after handling the product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical State	Solid
Color	White powder
Odor	Garlic-like odor

Physical and Chemical Properties

Molecular Weight	Not Available
Solubility	25g/L (water)
Flashpoint	N/A
Density	Not Available
pH	5-6 (reconstituted)
Boiling Point	Not Available
Freezing Point	Not Available
Melting Point	Not Available
Vapor Density	N/A
Vapor Pressure	N/A

SECTION 10: STABILITY AND REACTIVITY

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 (NOx), 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.

Sensitivity to static discharge/Dust exp.

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.).

SECTION 11: TOXICOLOGICAL INFORMATION

Routes of Entry	Ingestion, Inhalation, Eye Contact, Skin Contact
Eye Irritation	Not Available
Skin Irritation	*Mannitol* May cause skin irritation. L-(+)-Cysteine hydrochloride, monohydrate May cause skin irritation. *Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)* May cause skin irritation.
Respiratory Irritation	*Mannitol* May cause irritation of respiratory tract. L-(+)-Cysteine hydrochloride, monohydrate May cause irritation of respiratory tract. *Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)* May cause irritation of respiratory tract.
Sensitization	Not Available
Acute Toxicity Study	**Acute Oral** *L-(+)-Cysteine hydrochloride, monohydrate* LD50(rat): 1,890 mg/kg LD50(mouse): 1,660 mg/kg *Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)* LD50(rat): 123 mg/kg LD50(mouse): 80 mg/kg

Acute toxicity (other routes of administration)
Sodium Citrate Anhydrous
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
Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)
LDlo (rat, intravenous): 7 mg/kg

Repeated Dose Toxicity Not Available

Genetic Toxicity

Mannitol
Mutagenicity Assessment
Did not show mutagenic effects in animal experiments. Sodium Citrate Anhydrous
in vitro
Ames reverse-mutation assay -- negative
Mutagenicity Assessment
Several studies were conducted. Not mutagenic in AMES Test.
Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)
in vitro
Chromosome aberration test in vitro -- positive
CHO/HGPRT mammalian cell forward gene-mutation assay - negative
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 Exposure Experiences

Mannitol

Intravenous injection therapeutic use - Symptoms: diarrhea, 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.

Target Organs

Mannitol

kidney, lungs, cardiovascular system, endocrine system, gastrointestinal tract, immune system, central nervous system, inner ear (hearing)

Symptoms *Mannitol*
See "Human Experience".
Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)
redness and swelling of skin and eyes, taste disturbance, nausea, gastrointestinal disturbance, headache, chest pain

Other Toxicity Information Not Available

Section 12 ECOLOGICAL INFORMATION

Environmental Fate: *Mannitol*
Koc () : 5
High mobility in soil

Environmental Toxicity: **Ecotoxicological Information (Aquatic)**

Acute Toxicity to Fish
Sodium Citrate Anhydrous
LC50 (Poecilia reticulata, 96 H) : 18,000 mg/l
Acute Toxicity to Aquatic Invertebrates
Sodium Citrate Anhydrous
EC50 (Daphnia magna, 48 H) : 5,600 mg/l
Toxicity to aquatic plants
Sodium Citrate Anhydrous
EC50 (Chlorella vulgaris, 96 H) : 1,800 - 3,200 mg/l
Toxicity to microorganisms
Sodium Citrate Anhydrous
EC50 (Pseudomonas fluorescens, 8 H) : 1,800 - 3,200 mg/l

Ecotoxicological Information (Terrestrial)
Not Available

SECTION 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.

SECTION 14: TRANSPORT INFORMATION

US DOT Transportation Classification for All Modes

Proper shipping name N/A
This material is not a dangerous good for the purpose of transportation.

Hazard Class N/A

UN No. N/A

Packing Group N/A

Label Codes N/A

Marine Pollutant: No

Special Precautions NA

SECTION 15: REGULATORY INFORMATION

United States of America
OSHA Hazard Classification No OSHA Hazards

313 Toxic Release Inventory. No components listed
Listed Chemicals/Compounds

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/NDSL Not listed

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

Europe

EINECS/ELINCS Number	Mannitol: 200-711-8 Sodium Citrate Anhydrous: 200-675-3
Symbol(s)	Xi: Irritant
R-Phrase(s)	NA
S-Phrase(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).

SECTION 16: OTHER INFORMATION

MSDS preparation information

Prepared by Environment, Health and Safety 1-978-671-8673

Prepared on 11/4/2015

Other Information:

HMIS

Health	2
Flammability	0
Reactivity	0
Personal Protective Equipment	Not Determined

NFPA

Health	2
Fire	0
Reactivity	0
Special	Not Determined

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.