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 cause skin, eye, and/or respiratory irritation. May cause allergic reaction. Target 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.
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**

<table>
<thead>
<tr>
<th>Condition</th>
<th>First Aid Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye contact</td>
<td>Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Obtain medical attention.</td>
</tr>
<tr>
<td>Skin contact</td>
<td>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.</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Move to fresh air. Oxygen or artificial respiration if needed. Obtain medical attention.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Obtain medical attention. Do NOT induce vomiting. Never give anything by mouth to an unconscious person.</td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammable Properties</td>
<td>Not Available</td>
</tr>
<tr>
<td>Extinguishing Media</td>
<td>Suitable extinguishing media: Dry chemical, Water spray, Foam Unsuitable extinguishing media: Do NOT use water jet.</td>
</tr>
<tr>
<td>Protection of Firefighters</td>
<td>Specific hazards: Not available. Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus.</td>
</tr>
</tbody>
</table>
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.

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)

<table>
<thead>
<tr>
<th>Material</th>
<th>ACGIH</th>
<th>OSHA</th>
<th>NIOSH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copper(1+), tetrais[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Stannous Chloride Dihydrate</td>
<td>2mg/m³ TWA except tin hydride</td>
<td>2 mg/m³ TWA except tin hydride</td>
<td>100mg/m³ IDLH as tin 2mg/m³ as tin except oxides</td>
</tr>
</tbody>
</table>

Exposure Control Band

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

3 -- Material is assigned to Exposure Control Band 3 (range 20 - 50 μg/m³).

Lantheus Medical Imaging Exposure Guidelines Summary

Copper(1+), tetrais[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

<table>
<thead>
<tr>
<th>Physical State</th>
<th>Solid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>White powder</td>
</tr>
<tr>
<td>Odor</td>
<td>Garlic-like odor</td>
</tr>
</tbody>
</table>

Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Molecular Weight</th>
<th>Not Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility</td>
<td>25g/L (water)</td>
</tr>
<tr>
<td>Flashpoint</td>
<td>N/A</td>
</tr>
<tr>
<td>Density</td>
<td>Not Available</td>
</tr>
<tr>
<td>pH</td>
<td>5-6 (reconstituted)</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Not Available</td>
</tr>
<tr>
<td>Freezing Point</td>
<td>Not Available</td>
</tr>
<tr>
<td>Melting Point</td>
<td>Not Available</td>
</tr>
<tr>
<td>Vapor Density</td>
<td>N/A</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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-)*
- LD10 (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
  - 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

<table>
<thead>
<tr>
<th>Substance</th>
<th>ACGIH</th>
<th>OSHA</th>
<th>NTP</th>
<th>IARC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mannitol</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Sodium Citrate Anhydrous</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>L-(+)-Cysteine hydrochloride, monohydrate</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Copper(1+), tetrakis[1- (isocyano-kC) -2- methoxy-2- methylpropane]-, (T-4) - , tetrafluoroborate(1-)</td>
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</tr>
</tbody>
</table>

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

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.