# SAFETY DATA SHEET

Version 3.2 12/1/2022

## SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

**PRODUCT NAME:** Cardiolite®

**Synonyms** None

**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**
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

**Classification**
This material is not considered hazardous under 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

**Label Elements**
None Required

**Hazards not otherwise classified (HNOC)**
None identified

## SECTION 3: COMPOSITION INFORMATION ON INGREDIENTS

| Component | Concentration | CAS |
|---|---|---|
| Mannitol | 80.97% | 69-65-8 |
| 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 |

## 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 if symptoms occur.

**Skin contact**
Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention if symptoms occur.

**Inhalation**
Move to fresh air. If breathing is difficult, give oxygen. Obtain medical attention if symptoms occur.

**Ingestion**
Do not induce vomiting. Obtain medical attention if symptoms occur.

**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 affected may include: heart, bone marrow.

## SECTION 5: FIRE-FIGHTING MEASURES

**Flammable Properties**
May form combustible dust concentrations in air (during processing).

**Suitable Extinguishing Media**
Use agent most appropriate to extinguish surrounding fire.

**Protection of Firefighters**
In the event of fire, wear self-contained breathing apparatus.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

**Personal Precaution**
Use personal protective equipment as required. Ensure adequate ventilation. Avoid contact with skin, eyes or clothing

**Environmental Precautions**
Avoid release to the environment

**Methods for Containment and Clean Up**
Soak up with inert absorbent material. Keep in suitable, closed container for disposal.

## SECTION 7: HANDLING AND STORAGE

**Handling Precautions**
Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid contact with skin, eyes or clothing. Avoid ingestion and inhalation.

**Storage Conditions**
Store at room temperature. Protect against light. Keep away from heat, sparks and flames.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

**Exposure Limit(s)**

| Component | ACGIH | OSHA | NIOSH |
|---|---|---|---|
| Stannous Chloride Dihydrate | TWA: 2 mg/m$^3$ | TWA: 2 mg/m$^3$ | TWA: 2 mg/m$^3$ |

**Engineering Controls and Ventilation**
Ensure adequate ventilation, especially in confined areas. Ensure that eye wash stations and safety showers are close to the workstation location.

**Respiratory Protection**
Follow the OSHA respirator regulations found in 29 CFR 1910.134. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

**Eye/Face Protection**
Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133

**Skin and Body Protection**
Wear appropriate protective gloves and clothing to prevent skin exposure

**Hygiene Measures**

Wash hands and face before breaks and immediately after handling the product.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---|---|
| **Physical State** | Solid |
| **Appearance** | White powder (lyophilized) |
| **Odor** | Garlic like odor |
| **pH** | Not Available |
| **Molecular Weight** | Not Available |
| **Solubility** | Not Available |
| **Flashpoint** | Not Available |
| **Density** | Not Available |
| **Boiling Point** | Not Available |
| **Melting Point** | Not Available |
| **Melting Point** | Not Available |
| **Vapor Density** | Not Available |
| **Vapor Pressure** | Not Available |

## SECTION 10: STABILITY AND REACTIVITY

| | |
|---|---|
| **Stability** | Stable under normal conditions. |
| **Conditions to Avoid** | Not Available |
| **Incompatible Products** | Not Available |
| **Hazardous Decomposition Products** | None under normal use conditions |
| **Hazardous Reactions** | None under normal processing |

## SECTION 11: TOXICOLOGICAL INFORMATION

| | |
|---|---|
| **Routes of Entry** | Ingestion, Inhalation, Eye Contact, Skin Contact |
| **Eye Irritation** | Not Available |
| **Skin Irritation** | *Mannitol*<br>May cause skin irritation.<br>L-(+)-Cysteine hydrochloride, monohydrate<br>May cause skin irritation.<br>*Copper(1+), tetrakis[1-(isocyano-kC)-2-methoxy-2-methylpropane]-, (T-4)-, tetrafluoroborate(1-)*<br>May cause skin irritation. |
| **Respiratory Irritation** | *Mannitol*<br>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.

**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 edema, 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**: Not Available

**Environmental Toxicity**: 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.

## SECTION 14: TRANSPORT INFORMATION

**DOT**
Not Regulated

**IATA**
Not Regulated

## SECTION 15: REGULATORY INFORMATION

**United States of America**

| | |
|---|---|
| OSHA Hazard Classification | Not applicable |
| 313 Toxic Release Inventory. | No components listed on the SARA 313 inventory. |
| TSCA Inventory | Not listed. Food, drug and cosmetic products are exempt from TSCA. |

**International**

**Canada**

| | |
|---|---|
| WHMIS | Product is not according to Control Products Regulations. |
| DSL/NDSL | Not Listed |

**Mexico**
Mexico Classification Health classification – Slight Risk, Grade 1

**Europe**
EINECS/ELINCS Number Mannitol: 200-711-8
Sodium Citrate Anhydrous: 200-675-3

| | |
|---|---|
| R-Phrase(s) | NA |
| S-Phrase(s) | S22: Do not breathe dust.<br>S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.<br>S38: In case of insufficient ventilation, wear suitable respiratory equipment.<br>S45: In case of accident or if you feel unwell, seek medical advice immediately (show label where possible). |

Other Information: Medicinal products are exempt from classification and labeling requirements under EU Preparations Directive 1999/45/EC.

## SECTION 16: OTHER INFORMATION

**SDS preparation information**

| | |
|---|---|
| **Prepared by** | Environment, Health and Safety 1-978-671-8673 |
| **Prepared on** | 12/1/2022 |

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