SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Thallous Chloride TI-201 Injection

Version 3.1 11/4/2015

Product Uses This material is used as a medical imaging agent. It is a radioactive isotope of Thallium (TI-201).

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 Colorless liquid

Signal Word Danger!

Hazard Statements Radioactive

Precautionary Measures Avoid ingestion, inhalation, skin and eye contact. Care should be taken to minimize radiation exposure. Appropriate radiation shielding should be used. Keep material in a lead container. Avoid direct handling by using remote manipulation tools. Wash hands after handling to minimize exposure. Pregnant or nursing women should avoid exposure.

Potential Health Effects

<table>
<thead>
<tr>
<th>Eyes</th>
<th>Not Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin</td>
<td>Not Available</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Exposure to radioactive materials may produce adverse effects.</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Exposure to radioactive materials may produce adverse effects.</td>
</tr>
</tbody>
</table>
Target Organs Not Available

Signs and Symptoms Acute: diarrhea, nausea, vomiting, abdominal pain, thirst, fever, difficulty sleeping, tremors, delirium, confusion, convulsions, coma, death.
Chronic: Radioactive material: may cause cancer, adverse reproductive effects, embryo/fetal toxicity, hair loss, rash, skin effects, nail changes, pain, weakness, numbness, tingling, ataxia, constipation, vision changes, hallucinations.

Environmental Effects Refer to Section 12

SECTION 3: COMPOSITION INFORMATION ON INGREDIENTS

Active Substance Thallium-201

Common Name/Synonym: Thallium Chloride Injection; Thallium-201 Injection; Tl-201 Injection; Tl 201 Injection

Hazardous Components

<table>
<thead>
<tr>
<th>Component</th>
<th>Concentration</th>
<th>CAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thallium-201</td>
<td>&lt;0.1%</td>
<td>15064-65-0</td>
</tr>
</tbody>
</table>

Other Components

<table>
<thead>
<tr>
<th>Component</th>
<th>Concentration</th>
<th>CAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thallous Chloride</td>
<td>&lt;1%</td>
<td>55172-29-7</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>0.9%</td>
<td>7647-14-5</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>&lt;1%</td>
<td>100-51-6</td>
</tr>
<tr>
<td>Water</td>
<td>99%</td>
<td>7732-18-5</td>
</tr>
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</table>

Other Information Thallium-201 is a gamma emitting radionuclide with significant gamma rays up to 167.4 KeV. It also emits Mercury x-rays at a maximum energy of 80.3 KeV. The gamma ray constant is 33 microcoulombs/ Kg-MBq-hr (4.7R/mCi-hr.) at a distance of 1 cm. It has a physical half-life of 73.1 hours. The aqueous isotonic solution at the time of calibration contains 74 MBq/mL (2 mCi/mL) Thallous Chloride TI-201. The first half value thickness of lead (Pb) is 0.006cm. Sodium hydroxide and/or hydrochloric acid are used for pH adjustment.
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. Obtain medical attention. Dispose of contaminated clothing according to company procedures and governmental regulations for radioactive waste.

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 a radioactive isotope of Thallium (Tl-201). This product may cause: diarrhea, nausea, vomiting, abdominal pain, thirst, fever, difficulty sleeping, tremors, delirium, confusion, convulsions, coma, death. Radioactive material: may cause cancer, adverse reproductive effects, embryo/fetal toxicity, hair loss, rash, skin effects, nail changes, pain, weakness, numbness, tingling, ataxia, constipation, vision changes, hallucinations, increased liver enzymes, changes in ECG parameters, increase in heart rate, cardiac arrhythmias, increase in blood pressure, fetal toxicity, adverse effects on the newborn, decreased birth weight. This material may induce premature labor. Material not fully tested. Refer to Section 11. Pregnant or nursing women should avoid exposure.

Medical Surveillance  A pre-placement physical examination and history for employees with potential exposure to this compound is recommended. Baseline testing would include: EKG, a blood test for liver function. Based on opportunity for exposure and duration of exposure a periodic follow-up examination may be considered. This exam should be overseen by a physician thoroughly knowledgeable about both the toxicity of this compound and the extent of workplace exposure. It is recommended that the content be similar to the pre-placement exam.

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
Material is an aqueous solution. Not expected to be flammable.

Extinguishing Media
Suitable extinguishing media: Dry chemical, Water spray, Foam
Unsuitable extinguishing media: Do NOT use water jet.

Protection of Firefighters
Specific hazards: Radioactive. Heating can release hazardous gases.
Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus.
Hazardous Combustion Products: carbon oxides(COx), radioactive thallium, radioactive breakdown products, and, gaseous hydrogen chloride (HCl).
Further Information: HCl gas can form flammable or explosive mixtures with alcohols or metals. In the event of fire and/or explosion do not breathe fumes.

Other Information
Decontaminate protective clothing and equipment before reuse, or dispose of as radioactive waste. See Section 6.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions
Contact the company Radiation Safety Officer. Care should be taken to minimize radiation exposure. Handle as radioactive spill. 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. 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.

Environmental Precautions
Prevent release to drains and waterways. Prevent release to the environment.

Containment Methods
Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

Cleanup Methods
Contact the company Radiation Safety Officer. 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).
Isolate waste in sealed, clearly labeled containers and dispose of according to company procedures and governmental regulations. Care should be taken to minimize radiation exposure.

SECTION 7: HANDLING AND STORAGE

Handling Precautions
Avoid exposure - obtain special instructions before use. Contact the company Radiation Safety Officer. Care should be taken to minimize radiation exposure. Handling time should be kept to a minimum. Avoid formation of aerosols. Appropriate radiation shielding should be used. Use of syringe shields and tongs are recommended. Keep material in a lead container. Avoid direct handling by using remote manipulation tools. Obtain appropriate governmental licenses to possess and handle radioactive material. 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.

Storage Conditions
Store at controlled room temperature of 15 - 30°C. Storage and disposal of product should be controlled in a manner compliant with applicable governmental regulations pertaining to radionuclides. Store and handle in a designated area. Keep away from heat, sparks and flames.

Container Requirements
Store in sturdy containers appropriate to maintain the integrity of this material for its intended use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Exposure Limit(s)</th>
<th>Company Guideline</th>
<th>ACGIH</th>
<th>OSHA</th>
<th>NIOSH</th>
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<tr>
<td>Radionuclides</td>
<td>---</td>
<td>50 mSv</td>
<td>2.0 mCi</td>
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<td></td>
<td>Effective Dose, (annual)</td>
<td>Annual Limit (NRC - 10 CFR 20)</td>
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<td></td>
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<td>20 mSv</td>
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<td>Derived Air Conc. (NRC - 10 CFR 20)</td>
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<td></td>
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<td>50 mSv</td>
<td>Effective Dose, (annual)</td>
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<td></td>
<td>150 mSv</td>
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<td></td>
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<tr>
<td></td>
<td></td>
<td>(lens of eye), Annual</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Equivalent Dose 500 mSv</td>
<td>150 mSv</td>
<td>(lens of eye), Annual</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Skin), Annual</td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Equivalent Dose 500 mSv</td>
<td></td>
<td>Equivalent Dose 500 mSv</td>
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<tr>
<td></td>
<td></td>
<td>(hands and feet), Annual</td>
<td></td>
<td>(Skin), Annual</td>
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<td></td>
<td></td>
<td></td>
<td>Equivalent Dose</td>
</tr>
<tr>
<td>Exposure Limit(s) (continued)</td>
<td>Company Guideline</td>
<td>ACGIH</td>
<td>OSHA</td>
<td>NIOSH</td>
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<tr>
<td>------------------------------</td>
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<td>-------</td>
<td>------</td>
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<td>Equivalent Dose</td>
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<tr>
<td>0.5 mSv</td>
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<tr>
<td>(embryo/fetus),</td>
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</tr>
<tr>
<td>Monthly</td>
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<tr>
<td>Equivalent Dose</td>
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<tr>
<td>(abdomen of pregnant woman</td>
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</tr>
<tr>
<td>over course of pregnancy)</td>
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<td>1/20, Annual</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>(for pregnant woman</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>over course of pregnancy)</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

| Thallium-201                 | ---               | 0.1 mg/m³ TWA | ---   | ---   |

**Exposure Control Band**  Not Available

**Lantheus Medical Imaging Exposure Guidelines Summary**  Not Available

**Recommended Industrial Hygiene Monitoring Methods**
Contact the Lantheus Medical Imaging at 978-671-8672 or 978-671-8673.

**Engineering Controls and Ventilation**
Use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit.

**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 to control exposure to below the exposure limit, wear an approved supplied air respirator.

**Eye Protection**
Chemical safety goggles and face shields are recommended. 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 disposable coverall, polyethylene apron and sleeves, and shoe covers.

Hygiene
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>Liquid</th>
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</thead>
<tbody>
<tr>
<td>Color</td>
<td>Colorless</td>
</tr>
<tr>
<td>Odor</td>
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</tr>
</tbody>
</table>

Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Molecular Weight</td>
<td>Not Available</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble</td>
</tr>
<tr>
<td>Flashpoint</td>
<td>&gt;200°F</td>
</tr>
<tr>
<td>Density</td>
<td>Not Available</td>
</tr>
<tr>
<td>pH</td>
<td>4.5-7.5</td>
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<tr>
<td>Boiling Point</td>
<td>100 °C</td>
</tr>
<tr>
<td>Melting Point</td>
<td>0 °C</td>
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<tr>
<td>Vapor Density</td>
<td>Not Available</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>Not Available</td>
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</tbody>
</table>

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability
Stable under recommended storage conditions. Thallium-201 is a gamma emitting radionuclide with significant gamma rays up to 167.4 KeV. It also emits Mercury x-rays at a maximum energy of 80.3 KeV. The gamma ray constant is 33 micro-coulombs/Kg-MBq-hr (4.7R/mCi-hr.) at a distance of 1 cm. It has a physical half-life of 73.1 hours.

Conditions to Avoid
Heat, flames and sparks

Incompatible Products
Not Available

Hazardous Decomposition Products
Hazardous decomposition products formed under fire conditions: carbon oxides(COx), radioactive thallium, radioactive breakdown products, and, gaseous hydrogen chloride (HCl).
Hazardous Reactions

Hazardous polymerization does not occur.

SECTION 11: TOXICOLOGICAL INFORMATION

Routes of Entry
Ingestion, Inhalation, Eye Contact, Skin Contact

Eye Irritation
Not Available

Skin Irritation
Not Available

Respiratory Irritation
Not Available

Sensitization
Thallous Chloride: Dermal sensitizer

Acute Toxicity

Acute Oral
Thallous Chloride
LD₅₀ (rat): 55 mg/kg
LD₅₀ (mouse): 24 mg/kg
Minimum lethal dose (Human): 8 mg/kg

Repeated Dose Toxicity
Thallous Chloride
2 months Oral rat study: LOAEL = 10 ppm Effects include: sperm abnormalities.
26 Weeks subcutaneous rat study: LOAEL = 5 mg/kg Effects include: colitis, liver effects. Microscopic changes were observed in the following organs: liver, thyroid gland.

Genetic Toxicity
Thallous Chloride
Mutagenicity Assessment
This material was positive and negative in both in vitro and animal studies.

Carcinogenicity
Not Available

Carcinogenicity

Thallous Chloride
ACGIH: --- OSHA: --- NTP: --- IARC: ---

Radionuclides
ACGIH: --- OSHA: --- NTP: --- IARC: 1

Reproductive Toxicity
Not Available

Developmental Toxicity
Thallous Chloride
Oral (daily) Study of Embryo-Fetal Development (mouse)
Maternal effects include: maternal toxicity, post implantation loss. Fetal malformations were not observed; however, the material caused other adverse effects on the fetus.
### Human Experience

**Experiences with Human Exposure**

**Thallous Chloride**

Acute Overdose - Symptoms: hair loss, rash, nail changes, ataxia, inflammation of gastrointestinal tract, fever, cardiac irregularities, decreased concentration, coma, mental disturbance, muscle weakness.

Pregnant or nursing individuals Acute Overdose - Symptoms: fetal toxicity, adverse effects on the newborn.

### Target Organs

**Thallous Chloride**: liver, kidney, peripheral nervous system, skin

### Symptoms

**Thallous Chloride**

See "Human Experience".

### Other Information

Toxicology information provided in this MSDS is based on a different salt form. The toxicological data presented is derived from a structurally or pharmacologically similar compound.

#### Section 12 ECOLOGICAL INFORMATION

**Environmental Fate:** Not Available

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

**Acute Toxicity to Aquatic Invertebrates**

**Thallous Chloride**

EC50 (Daphnia magna (Water flea), 48 H) : 61 ug/l.

Ecotoxicological Information (Terrestrial) Not available

#### SECTION 13: Disposal Considerations

**Advice on Disposal Packaging**

Segregate and label radioactive waste. Disposal should be in and 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.
US DOT Transportation Classification for All Modes
The classification for transportation of radioactive materials will depend on the specific activity level of the material, type of isotope, as well as the quantity shipped. Specific site procedures should be followed for shipping radioactive materials or seek advice from your site radiation safety officer.

SECTION 15: REGULATORY INFORMATION

United States of America
OSHA Hazard Classification
No OSHA Hazards, Radioactive—This regulation does not address hazards related to radioactivity.

CERCLA/SARA RQ
Thallium-201       RQ = 1 lb
Thallium-201       RQ = 0.454 kg
Thallium-201       RQ = 1000 Ci
Thallium-201       RQ = 37 TBq

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.

California Prop 65
Carcinogen Radionuclides

International
Canada
WHMIS
Finished medicinal products are exempt from classification and labeling requirements under the Canadian Hazardous Products Act and Controlled Products Regulations.
Note: This regulation does not address hazards related to radioactivity.

DSL/NDSL
Not listed

Europe
EINECS/ELINCS Number
Sodium Chloride: 231-598-3
Benzy1 Alcohol: 202-859-9
Water: 231-791-2

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

Health classification - Minimal hazard - 0 - Substances that do not pose a hazard under emergency conditions other than that of ordinary combustible materials.

Note: This regulation does not address hazards related to radioactivity.

**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: 0
- Flammability: 0
- Reactivity: Not Determined
- Personal Protective Equipment: See Section 8

**NFPA**

- Health: 0
- Fire: Not Determined
- Reactivity: Not Determined
- 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.