SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Thallous Chloride Tl-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 (Tl-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

Eyes	Not Available
Skin	Not Available
Ingestion	Exposure to radioactive materials may produce adverse effects.
Inhalation	Exposure to radioactive materials may produce adverse effects.

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

Component	Concentration	CAS
Thallium-201	<0.1%	15064-65-0
Other Components		
Thallous Chloride	<1%	55172-29-7
Sodium Chloride	0.9%	7647-14-5
Benzyl Alcohol	<1%	100-51-6
Water	99%	7732-18-5

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 Tl-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 work place 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

Exposure Limit(s)	Company Guideline	ACGIH	OSHA	NIOSH
Radionuclides	---	50 mSv Effective Dose, (annual) 20 mSv Effective Dose, 5 years 150 mSv (lens of eye), Annual Equivalent Dose 500 mSv (Skin), Annual Equivalent Dose 500 mSv (hands and feet), Annual	2.0 mCi Annual Limit (NRC - 10 CFR 20) 0.000001 µCi/ml Derived Air Conc. (NRC - 10 CFR 20) 50 mSv Effective Dose, (annual) 150 mSv (lens of eye), Annual Equivalent Dose 500 mSv (Skin), Annual Equivalent Dose	---

Exposure Limit(s) (continued)	Company Guideline	ACGIH	OSHA	NIOSH
		Equivalent Dose 0.5 mSv (embryo/fetus), Monthly Equivalent Dose 2 mSv (abdomen of pregnant woman over course of pregnancy) 1/20, Annual Limit on Intake, as ionizing radiation, (for pregnant woman over course of pregnancy)	15 mg/m3 TWA total dust 5 mg/m3 TWA	
Thallium-201	---	0.1 mg/m^3 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

Physical State	Liquid
Color	Colorless
Odor	Odorless

Physical and Chemical Properties

Molecular Weight	Not Available
Solubility	Soluble
Flashpoint	>200F
Density	Not Available
pH	4.5-7.5
Boiling Point	100 °C
Melting Point	0 °C
Vapor Density	Not Available
Vapor Pressure	Not Available

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
LDlo(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.

Carcinogentiy Not Available

Carcinogenicity

	ACGIH	OSHA	NTP	IARC
Thallous Chloride	---	---	---	---
Radionuclides	---	---	---	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 individiuals 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.

SECTION 14: TRANSPORT INFORMATION

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 Benzyl 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.