Material Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION	
Product Information	
Product name	Thallous Chloride Tl-201 Injection
Version	2.0, 01/02/2008
Active substance	Thallium-201
Synonyms	Thallium Chloride Injection; Thallium-201 Injection; Tl-201 Injection; Tl 201 Injection
Product Uses	This material is used as a medical imaging agent. It is a radioactive isotope of Thallium (Tl-201).
Company/Undertaking Identification	
Address	**Lantheus Medical Imaging** 331 Treble Cove Road Billerica, MA 01862 United States of America 1-800-299-3431
Emergency Phone Number	CHEMTREC 1-800-424-9300. For all international transportation emergencies call CHEMTREC at 1-703-527-3887. Collect calls accepted.

2. COMPOSITION/INFORMATION ON INGREDIENTS		
Components	Concentration	CAS-No.
Hazardous components		
Thallium-201	<0.1 %	15064-65-0
Other ingredients		
Thallous Chloride	<0.1 %	55172-29-7
Sodium Chloride	<1 %	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 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. 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.		

3. HAZARDS IDENTIFICATION	
Emergency Overview	
Appearance	liquid : colourless
Signal Word	Danger
Hazard Statements	Radioactive.

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3. HAZARDS IDENTIFICATION	
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: diarrhoea, 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

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	Take off 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	Do NOT induce vomiting. Consult a physician if necessary. Never give anything by mouth to an unconscious person.
Notes to Physician	This material is used as a medical imaging agent. It is a radioactive isotope of Thallium (Tl-201). This product may cause: diarrhoea, 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.

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4. FIRST AID MEASURES	
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.

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. 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. Heating can release hazardous gases.

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.

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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.
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.

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 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)	2.0 mCi Annual Limit (NRC - 10 CFR 20) 0.000001 µCi/ml Derived Air Concentration (NRC - 10 CFR 20) 50 mSv Effective Dose, (annual) 150 mSv (lens of eye), Annual Equivalent Dose 500 mSv (Skin), Annual Equivalent Dose 15 mg/m3 TWA total dust 5 mg/m3 TWA	--

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION				
Thallium-201	--	0.1 mg/m3 TWA	--	--
Exposure Control Band	Not available			
Lantheus MI Exposure Guidelines Summary	Not available			
Recommended Industrial Hygiene Monitoring Methods	Contact the Lantheus Medical Imaging Radiation Protection Office at 978-671-8672 or 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.			

9. PHYSICAL AND CHEMICAL PROPERTIES	
Appearance	
Physical State	liquid
Color	colourless
Form	Not available
Descriptive properties	
Molecular Weight	Not available
Molecular formula	Not applicable
Bulk density	Not available
Evaporation rate	Not available
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Log Octanol/Water Partition Coeff [log Kow]	Not available
Surface Tension	Not available
Odor	odourless
Odor Threshold	Not available
pH	4.5 - 7.5
pKa	Not available
Particle Size	Not available
Solubility, Water	soluble
Specific Gravity/ Relative density	Not available
Viscosity	Not available

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9. PHYSICAL AND CHEMICAL PROPERTIES	
Thermal/Stability properties	
Autoignition temperature	Not available
Boiling Point	100 °C
Thermal decomposition	Not available
Explosive Limits, LEL	Not available
Explosive limits, UEL	Not available
Explosiveness	Not available
Flammability	Not available
Flash point	Not available
Melting Point	0 °C
Oxidizing Potential	Not available
Vapor Properties	
Vapor Density	Not available
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

10. STABILITY AND REACTIVITY	
Stability	
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 polymerisation does not occur.

11. TOXICOLOGICAL INFORMATION	
Routes of Entry	Ingestion, Inhalation, Eye contact, Skin contact
Eye Irritation	Not available
Skin Irritation	Not available
Respiratory Irritation	Not available
Sensitisation	Thallous Chloride dermal sensitizer.
Acute Toxicity Study	**Acute Oral** Thallous Chloride LDlo(rat): 55 mg/kg LD50(mouse): 24 mg/kg Minimum lethal dose(Human): 8 mg/kg

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11. TOXICOLOGICAL INFORMATION

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	**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, postimplantation 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 Toxicity Information	Not available
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.

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12. ECOLOGICAL INFORMATION

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
Chemical fate information	Not available

13. DISPOSAL CONSIDERATIONS

Advice On Disposal And Packaging	Segregate and label radioactive waste. 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. This information presented only applies to the material as supplied.
Other information	Disposal by incineration is recommended.

14. TRANSPORT INFORMATION

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.

15. REGULATORY INFORMATION

United States of America		
OSHA Hazard Classification	No OSHA Hazards, Note: 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 = 1,000 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.	
Mexico		
Mexico Classification	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.	
Europe		
EINECS/ELINCS Number	Sodium Chloride: 231-598-3 Benzyl Alcohol: 202-859-9 Water: 231-791-2	

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15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

MSDS preparation information

Prepared by	Environmental Health & Safety 1-978-671-8673
Prepared on	01/02/2007
	This Safety Data Sheet has been revised. This MSDS has been reformatted in a new electronic system. This data sheet contains changes from the previous version in section(s): All.

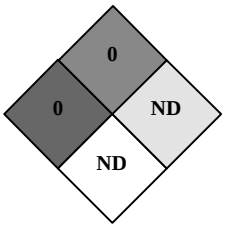
Other information

HMIS

Health	0
Flammability	0
Reactivity	Not Determined (ND)
Personal protective equipment	See Section 8.

NFPA

Health	0
Fire	0
Reactivity	ND
Special	ND



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.

End of Safety Data Sheet