

SAFETY DATA SHEET



1. Identification

Product identifier	THALLOUS CHLORIDE TI 201 INJECTION
Other means of identification	
SDS number	TC201
Recommended use	This product as solid is radioactive. Thallous Chloride TI 201 Injection is a diagnostic radiopharmaceutical indicated for myocardial perfusion imaging as well as localization of sites of parathyroid hyperactivity.
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Supplier	
Company name	Curium US LLC
Address	2703 Wagner Place Maryland Heights, MO 63043 United States
Telephone number	Customer Service 888-744-1414
E-mail	NuclearMedicine@curiumpharma.com
Emergency telephone number:	24 Hour Emergency 314-595-3700 Chemtrec 800-424-9300

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Reproductive toxicity Effects on or via lactation
OSHA defined hazards	Not classified.
Label elements	
Hazard symbol	None.
Signal word	None.
Hazard statement	May cause harm to breast-fed children. RADIOACTIVE MATERIAL. HANDLE ACCORDING TO ALL FEDERAL AND STATE REGULATIONS GOVERNING THE USE OF RADIOACTIVE MATERIAL.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not breathe mist/vapors. Do not eat, drink or smoke when using this product. Avoid contact during pregnancy/while nursing. Wash thoroughly after handling.
Response	If exposed or concerned: Get medical advice/attention.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.

Supplemental information

As per 29 CFR 1910.1200(b)(6)(xi), ionizing and nonionizing radiation are outside the scope and application of the Hazard Communication Standard, although the radioactive material should be considered the principle hazard of the material. This material should only be handled by trained individuals in conformance with the requirements of applicable regulations. Radioactive materials in the US are not subject to OSHA regulations. The US Nuclear Regulatory Commission (NRC) is the Federal agency responsible for protecting the health and safety of the public and the environment by licensing and regulating the civilian uses of the radioactive materials.

CAUTION! RADIOACTIVE MATERIAL. Read Package Insert prior to use. Promptly remove any contamination from the skin, eyes, or clothing. Radioactive drugs must be handled by qualified personnel in conformity with regulations appropriate to the government agency authorized to license the use of this radionuclide. The vial containing the drug should be kept within its container or within heavier shielding. Avoid contact with the radioactive contents which would cause unnecessary exposure to radiation.

Drugs that increase or decrease myocardial blood flow or potassium uptake might correspondingly alter the biodistribution of Thallous Chloride TI 201.

Pregnancy: Administer only if clearly needed. Nursing Mothers: Discontinue nursing or express and discard milk for a minimum of 2 weeks after administration. Pediatrics: Safety and effectiveness have not been established in pediatric patients.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
WATER	7732-18-5	99 %
BENZYL ALCOHOL	100-51-6	0.9 %
SODIUM CHLORIDE	7647-14-5	0.9 %
THALLOUS CHLORIDE TL-201	55172-29-7	0.001 %

Composition comments

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

Inhalation

Call a POISON CENTER or doctor/physician. Notify radiation safety personnel immediately. Remove to fresh air, support breathing by usual methods if necessary. Stand upwind if possible. Evaluate and document the amount of material inhaled and seek medical attention for radiation intake.

Skin contact

Wash off with soap and water. Always blot dry. Do not abrade skin. Notify radiation safety personnel.

Eye contact

Immediately flush eyes with plenty of water for at least 15 minutes. Notify radiation safety personnel.

Ingestion

Call a POISON CENTER or doctor/physician. Notify radiation safety personnel immediately. Rinse mouth. The amount of material ingested should be assessed and documented.

Most important symptoms/effects, acute and delayed

Serious adverse reactions associated with myocardial perfusion testing including myocardial infarction, arrhythmia, hypotension, bronchoconstriction, and cerebrovascular events have been reported in patients who have undergone stress testing.

The most frequently reported reactions were itching, nausea, vomiting, mild diarrhea, tremor, shortness of breath, chills, fever, conjunctivitis, sweating, and blurred vision.

Following the administration of Thallous Chloride TI 201 Injection, anaphylactoid reactions have been reported (characterized by cardiovascular, respiratory and cutaneous symptoms), some considered serious and severe enough to require treatment. Hypotension, pruritus, flushing, and diffuse rash which responds to antihistamines have been reported. Direct contact with eyes may cause temporary irritation.

Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed. Drugs that increase or decrease myocardial blood flow or potassium uptake might correspondingly alter the biodistribution of Thallous Chloride TI 201. Pregnancy: Administer only if clearly needed. Nursing Mothers: Discontinue nursing or express and discard milk for a minimum of 2 weeks after administration. Pediatrics: Safety and effectiveness have not been established in pediatric patients.
General information	IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.
5. Fire-fighting measures	
Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Radioactive. During fire, gases hazardous to health may be formed such as: May emit radioactive fumes containing TI-201 when heated to decomposition.
Special protective equipment and precautions for firefighters	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.
Fire fighting equipment/instructions	Ensure and follow all guidance provided in handling fire involving radioactive materials. Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers. In case of fire and/or explosion do not breathe fumes.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.
6. Accidental release measures	
Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not breathe mist or vapor. Follow all guidances provided by NRC or equivalent authority. In the case of a leak/release of this material, wear protective clothing, a personal respirator, chemical-resistant rubber gloves, chemical safety goggles, and shoe covers. If on site, follow the site licence requirements for the disposal of radioactive material or proceed as directed by the local Radiation Safety Officer. Ventilate the area, allowing sufficient time for several air exchanges. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. If possible, place material in a suitable hermetically sealed lead container. Clean surface thoroughly to remove residual contamination. Following product recovery, flush area with water. All cleanup operations should be performed according to the Standard Operating Procedures (SOPs) established for your facility in accordance with NRC or other applicable local, state or federal regulations. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
7. Handling and storage	
Precautions for safe handling	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Follow all guidances provided by the US Nuclear Regulatory Commission in the US or equivalent authority in your country and your radiation safety personnel. Appropriate radiation shielding should be used. Provide adequate ventilation. Do not breathe mist or vapor. Do not get in eyes, on skin, or on clothing. Avoid contact during pregnancy/while nursing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Should be handled in closed systems, if possible. Wear protective clothing, including chemical safety goggles and chemical-resistant waterproof gloves. Wash hands and forearms after handling. Observe good industrial hygiene practices. All shippers and consignees, as well as handlers of this material must possess a valid radioisotope licence issued by the appropriate federal or state authority. Handling time should be kept to a minimum and appropriate radiation shielding should be used. Avoid direct handling by using remote manipulation tools, syringe shields and tongs.
Conditions for safe storage, including any incompatibilities	Store at controlled room temperature at 20–25 °C (68-77°F). Store locked up. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). Storage and disposal of product should be controlled in a manner which is in compliance with the appropriate regulations of the federal or state government agency authorized to license the use of this radionuclide.

8. Exposure controls/personal protection

Occupational exposure limits

US. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value
BENZYL ALCOHOL (CAS 100-51-6)	TWA	44.2 mg/m ³ 10 ppm

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

The specific gamma ray constant for Thallous Chloride TI 201 is 9 E -6 µCi/mL of air.

Appropriate engineering controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection

Chemical resistant gloves. Suitable gloves can be recommended by the glove supplier.

Skin protection

Other

Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended.

Respiratory protection

No personal respiratory protective equipment normally required.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Follow all guidances provided by the US Nuclear Regulatory Commission or equivalent authority and your radiation safety personnel. When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Clear, colorless liquid in a 10 mL glass vial.

Physical state

Liquid.

Form

Liquid.

Color

Colorless.

Odor

Not available.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

44.99 °F (7.22 °C) estimated
32 °F (0 °C)

Initial boiling point and boiling range

212 °F (100 °C)

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

Not available.

Flammability limit - upper (%)

Not available.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor pressure

-0.0005 hPa estimated

Vapor density

Not available.

Relative density

1.603 g/cm³ estimated

Solubility(ies)	
Solubility (water)	Soluble.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	Specific Activity: 213 mCi/µg of Thallium on the calibration date and time.
Concentration	Concentration: 1 mCi/mL on the calibration date and time.
Density	1.60 g/cm ³ estimated
Explosive properties	Not explosive.
Half-Life	72.9 Hours (Radioactive)
Oxidizing properties	Not oxidizing.
Percent volatile	99.11 % estimated
Radioactivity	2, 4, 8 or 9 mCi/vial on the calibration date and time.
VOC	99.11 % estimated

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	May emit radioactive fumes containing TI-201 when heated to decomposition.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Exposure to radioactive materials may produce adverse effects. Thallous Chloride does not easily become airborne.
Skin contact	Exposure to radioactive materials may produce adverse effects. May be irritating to the skin.
Eye contact	Direct contact with eyes may cause temporary irritation. Exposure to radioactive materials may produce adverse effects.
Ingestion	Exposure to radioactive materials may produce adverse effects. May cause asymptomatic physiological uptake by specific target organs or tissues.

Symptoms related to the physical, chemical and toxicological characteristics

Serious adverse reactions associated with myocardial perfusion testing including myocardial infarction, arrhythmia, hypotension, bronchoconstriction, and cerebrovascular events have been reported in patients who have undergone stress testing.

The most frequently reported reactions were itching, nausea, vomiting, mild diarrhea, tremor, shortness of breath, chills, fever, conjunctivitis, sweating, and blurred vision.

Following the administration of Thallous Chloride TI 201 Injection, anaphylactoid reactions have been reported (characterized by cardiovascular, respiratory and cutaneous symptoms), some considered serious and severe enough to require treatment. Hypotension, pruritus, flushing, and diffuse rash which responds to antihistamines have been reported. Direct contact with eyes may cause temporary irritation.

Information on toxicological effects

Acute toxicity May cause asymptomatic physiological uptake by specific target organs or tissues.

Components	Species	Test Results
BENZYL ALCOHOL (CAS 100-51-6)		
<u>Acute</u>		
Dermal		
LD50	Guinea pig	<= 5 ml/kg
	Rabbit	2000 mg/kg

Components	Species	Test Results
Inhalation		
LC100	Rat	200 - 300 mg/l, 8 Hours
LC50	Rat	1000 mg/l, 8 Hours
Oral		
LD50	Mouse	1580 mg/kg
	Rabbit	1940 mg/kg
	Rat	1230 - 3100 mg/kg
Other		
LD50	Guinea pig	>= 400 mg/kg
	Mouse	324 mg/kg
	Rat	<= 0.5 ml/kg 53 mg/kg
SODIUM CHLORIDE (CAS 7647-14-5)		
Acute		
Oral		
LD50	Mouse	4000 mg/kg
	Rat	3000 mg/kg
Other		
LD50	Mouse	2602 mg/kg
Skin corrosion/irritation	May cause skin irritation.	
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Respiratory or skin sensitization		
Respiratory sensitization	Following the administration of Thallous Chloride TI 201 Injection, anaphylactoid reactions have been reported (characterized by cardiovascular, respiratory and cutaneous symptoms), some considered serious and severe enough to require treatment. Hypotension, pruritus, flushing, and diffuse rash which responds to antihistamines have been reported.	
Skin sensitization	Following the administration of Thallous Chloride TI 201 Injection, anaphylactoid reactions have been reported (characterized by cardiovascular, respiratory and cutaneous symptoms), some considered serious and severe enough to require treatment. Hypotension, pruritus, flushing, and diffuse rash which responds to antihistamines have been reported.	
Germ cell mutagenicity	No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential or whether this drug affects fertility in males or females. Gamma radiation is a potential mutagen to human. The health risks associated with chronic radiation exposure (cancer, leukemia, genetic and teratogenic effects) are believed to involve levels of radiation exposure which are much higher than those permitted occupationally.	
Carcinogenicity	No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential or whether this drug affects fertility in males or females. Gamma radiation is carcinogenic to humans. The health risks associated with chronic radiation exposure (cancer, leukemia, genetic and teratogenic effects) are believed to involve levels of radiation exposure which are much higher than those permitted occupationally.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not listed.		
NTP Report on Carcinogens		
Not listed.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)		
Not regulated.		
Reproductive toxicity	There are no adequate or well-controlled studies of Thallous Chloride TI 201 Injection use in pregnant women. Studies using human placentas demonstrate that Thallous Chloride TI 201 crosses the placenta. Animal reproductive studies have not been conducted. Administer Thallous Chloride TI 201 Injection to a pregnant woman only if clearly needed.	
	Thallous Chloride TI 201 is excreted in human milk. Advise patients who continue to breastfeed to express and discard milk for a minimum of 2 weeks after administration of Thallous Chloride TI 201. Minimize close contact with infants if the administered dose would result in an effective dose greater than 1 mSv (0.1 rem) to the infant.	

Specific target organ toxicity - single exposure	Based on available data, the classification criteria are not met.
Specific target organ toxicity - repeated exposure	Based on available data, the classification criteria are not met.
Aspiration hazard	Due to partial or complete lack of data the classification is not possible.
Chronic effects	The health risks associated with chronic radiation exposure (cancer, leukemia, genetic and teratogenic effects) are believed to involve levels of radiation exposure which are much higher than those permitted occupationally.
Further information	No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential or whether this drug affects fertility in males or females.

12. Ecological information

Ecotoxicity This material has not been tested for environmental effects.

Components	Species	Test Results
BENZYL ALCOHOL (CAS 100-51-6)		
Aquatic		
Fish	LC50	Bluegill (<i>Lepomis macrochirus</i>) 10 mg/l, 96 hours
SODIUM CHLORIDE (CAS 7647-14-5)		
Aquatic		
Crustacea	EC50	Water flea (<i>Daphnia magna</i>) 340.7 - 469.2 mg/l, 48 hours
Fish	LC50	Fathead minnow (<i>Pimephales promelas</i>) 6020 - 7070 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of any ingredients in the mixture.

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)	
BENZYL ALCOHOL (CAS 100-51-6)	1.1

Mobility in soil No data available.

Other adverse effects An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

13. Disposal considerations

Disposal instructions Thallous Chloride TI 201 Injection is Radioactive Waste until the activity has decayed to non-detectable levels. Radioactive waste must be handled in accordance with procedures established by your Radiation Safety Officer, NRC and other applicable regulations. If medical waste is involved, such as blood, blood products, or sharps, the waste must be handled as a biohazard and disposed of accordingly. If not a biohazard, consult local, state and federal regulations for proper disposal.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations.

Contaminated packaging Dispose in accordance with all applicable regulations.

14. Transport information

DOT

UN number	UN2915
UN proper shipping name	Radioactive material, Type A package
Transport hazard class(es)	
Class	7
Subsidiary risk	-
Label(s)	7
Packing group	Not available.
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.
Special provisions	A56, W7, W8
Packaging exceptions	None
Packaging non bulk	415, 418, 419
Packaging bulk	415, 418, 419

IATA

UN number	UN2915
UN proper shipping name	Radioactive material, Type A package
Transport hazard class(es)	
Class	7
Subsidiary risk	-
Label(s)	7
Packing group	Not available.
Environmental hazards	No.
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

IMDG

UN number	UN2915
UN proper shipping name	Radioactive material, Type A package
Transport hazard class(es)	
Class	7
Subsidiary risk	-
Label(s)	7
Packing group	Not available.
Environmental hazards	
Marine pollutant	No.
EmS	Not available.
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations Radioactive materials in the US are not subject to OSHA regulations. The US Nuclear Regulatory Commission (NRC) is the Federal agency responsible for protecting the health and safety of the public and the environment by licensing and regulating the civilian uses of the radioactive materials.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

Toxic Substances Control Act (TSCA) One or more components of the mixture are not on the TSCA 8(b) inventory or are designated "inactive".

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

Classified hazard categories Reproductive toxicity

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

BENZYL ALCOHOL (CAS 100-51-6)

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

BENZYL ALCOHOL (CAS 100-51-6)

US. Rhode Island RTK

Not regulated.

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 25-January-2019

Revision date 15-February-2019

Version # 02

Disclaimer Curium US LLC cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.