

SAFETY DATA SHEET

1. Identification

Product identifier	Ultratag™ RBC Kit for the preparation of Technetium Tc 99m–Labeled Red Blood Cells
Other means of identification	
SDS number	URBCK
Synonyms	Tc-99m RBC Tagging Kit
Recommended use	The content of this kit as sold is non radioactive. Ultratag™ RBC (kit for the preparation of technetium Tc 99m-labeled red blood cells) is a sterile, nonpyrogenic, diagnostic kit for the in vitro preparation of technetium Tc 99m-labeled red blood cells (Not included in this kit). Technetium Tc 99m-labeled red blood cells are used for blood pool imaging, including cardiac first pass and gated equilibrium imaging and for detection of sites of gastrointestinal bleeding.
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Supplier	
Company name	Curium Canada Inc.
Address	2572 Daniel-Johnson Boulevard Offices 245-249, 2nd Floor Laval, QC H7T 2R3 Canada
Telephone number	Customer Service phone number: 866-885-5988
E-mail	NuclearMedicine@curiumpharma.com
Emergency telephone number:	24 Hour Emergency 314-595-3700 Chemtrec 800-424-9300

2. Hazard identification

Physical hazards	Not classified.	
Health hazards	Serious eye damage/eye irritation	Category 2A
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 3
	Hazardous to the aquatic environment, long-term hazard	Category 3

Label elements



Signal word	Warning
Hazard statement	Causes serious eye irritation. Harmful to aquatic life with long lasting effects.
Precautionary statement	
Prevention	Wear eye protection/face protection. Wash thoroughly after handling. Avoid release to the environment.
Response	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Other hazards	None known.
Supplemental information	This safety data sheet covers the content of the kit as sold (non radioactive) prior to reconstitution.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Citric acid		77-92-9	0.9 (SII)
DEXTROSE , ANHYDROUS		50-99-7	59.5 (RV), 1.2 (SII)
SODIUM CITRATE DIHYDRATE		6132-04-3	39.7 (RV), 3.3 (SII)
Sodium hypochlorite		7681-52-9	0.1 (SI)
STANNOUS CHLORIDE		7772-99-8	0.8 (RV)
Water		7732-18-5	99.9 (SI), 95 (SII)

RV: Reaction Vial.

SI: Syringe I.

SII: Syringe II.

Composition comments

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

Each kit consists of three separate nonradioactive components:

1. A 10 milliliter reaction vial containing: Stannous Chloride, Dihydrate ($\text{SnCl}_2 \cdot 2\text{H}_2\text{O}$) – 50 ug minimum; Stannous Chloride, Dihydrate ($\text{SnCl}_2 \cdot 2\text{H}_2\text{O}$) – 96 ug theoretical; Tin Chloride (Stannous and Stannic), Dihydrate (as $\text{SnCl}_2 \cdot 2\text{H}_2\text{O}$) – 105 ug maximum; Sodium Citrate, Dihydrate – 3.67 mg; and Dextrose, Anhydrous – 5.50 mg.

Prior to lyophilization, the pH is adjusted to 7.1 to 7.2 with sodium hydroxide. The contents of the vial are lyophilized and stored under argon.

2. Syringe I contains: Sodium Hypochlorite – 0.6 mg in Sterile Water for Injection.

The total volume of this syringe is 0.6 mL. Sodium hydroxide may have been added for pH adjustment. The pH of this solution is 11 to 13. The syringe must be protected from light to prevent degradation of the light-sensitive sodium hypochlorite.

3. Syringe II contains: Citric Acid, Monohydrate – 8.7 mg; Sodium Citrate, Dihydrate – 32.5 mg; and Dextrose, Anhydrous – 12.0 mg in Sterile Water for Injection.

The total volume of this syringe is 1.0 mL. The pH range of this solution is adjusted to 4.5 to 5.5 with sodium citrate or citric acid.

4. First-aid measures

Inhalation

Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact

Remove contaminated clothing immediately and wash skin with soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

Eye contact

Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention if irritation develops and persists.

Ingestion

Rinse mouth. Get medical attention if symptoms occur. Never give anything by mouth to a victim who is unconscious or is having convulsions.

Most important symptoms/effects, acute and delayed

Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

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	When heated to decomposition, substance may emit oxides of carbon and corrosive fumes of hydrochloric acid.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers.
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. Local authorities should be advised if significant spillages cannot be contained. Ensure adequate ventilation. Avoid contact with eyes and prolonged skin contact. Avoid dust formation. 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. If possible, place material in a suitable hermetically sealed lead container. Following product recovery, flush area with water. 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	Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapours/spray. Avoid contact with eyes. Avoid contact with skin. Avoid prolonged exposure. Provide adequate ventilation. When using, do not eat, drink or smoke. Wear personal protective equipment. Wash thoroughly after handling. Observe good industrial hygiene practices. Avoid release to the environment.
Conditions for safe storage, including any incompatibilities	<p>Syringe I should be protected from light if not stored in the kit tray. The drug should be stored at controlled room temperature (20- 25°C) or (68-77°F) both prior to and following reconstitution with Sodium Pertechnetate Tc-99m, and discarded six (6) hours from the time of preparation. After reconstitution, handling time should be kept to a minimum and appropriate shielding should be used. Avoid direct handling by using remote manipulation tools, syringe shields and tongs.</p> <p>Store locked up. Store in original tightly closed container. Keep container tightly closed. Store in a well-ventilated place. The kit should be stored at controlled room temperature 20-25°C (68-77°F). Syringe I should be protected from light if not stored in the kit tray. Store away from incompatible materials (see section 10 of the SDS).</p> <p>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.</p>

8. Exposure controls/personal protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

Components	Type	Value
STANNOUS CHLORIDE (CAS 7772-99-8)	TWA	2 mg/m3

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value
STANNOUS CHLORIDE (CAS 7772-99-8)	TWA	2 mg/m3

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value
STANNOUS CHLORIDE (CAS 7772-99-8)	TWA	2 mg/m3

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

Components	Type	Value
STANNOUS CHLORIDE (CAS 7772-99-8)	TWA	2 mg/m3

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value
STANNOUS CHLORIDE (CAS 7772-99-8)	TWA	2 mg/m ³

Canada. Quebec OELs. (Ministry of Labor - Regulation respecting occupational health and safety)

Components	Type	Value
STANNOUS CHLORIDE (CAS 7772-99-8)	TWA	2 mg/m ³

Canada. Saskatchewan OELs (Occupational Health and Safety Regulations, 1996, Table 21)

Components	Type	Value
STANNOUS CHLORIDE (CAS 7772-99-8)	15 minute	4 mg/m ³
	8 hour	2 mg/m ³

Biological limit values	No biological exposure limits noted for the ingredient(s).
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. Provide eyewash station.
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.
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	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	Small, dry white crystals clinging to inside of 10 mL glass vial and 2 syringes partially filled with colorless solution.
Physical state	Solid, Liquid.
Form	Crystals. Solution.
Colour	White.
Odour	Odourless.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	0 °C (32 °F) reconstituted.
Initial boiling point and boiling range	100 °C (212 °F) reconstituted.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
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.
Vapour pressure	Not available.

Vapour density	Not available.
Relative density	Not available.
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	
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

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. Syringe I is sensitive to light.
Possibility of hazardous reactions	Will not occur.
Conditions to avoid	Light. Contact with incompatible materials.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	Carbon oxides. Hydrogen chloride.

11. Toxicological information

Information on likely routes of exposure

Inhalation	May be harmful if inhaled. Inhalation of dusts may cause respiratory irritation.
Skin contact	May be harmful in contact with skin. May be irritating to the skin.
Eye contact	Causes serious eye irritation.
Ingestion	May be harmful if swallowed. May cause discomfort if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

Information on toxicological effects

Acute toxicity May be harmful if swallowed. May be harmful if absorbed through skin. May be harmful if inhaled. Causes eye irritation.

Components	Species	Test Results
Citric acid (CAS 77-92-9)		
Acute		
Oral		
LD50	Rat	6730 mg/kg
DEXTROSE , ANHYDROUS (CAS 50-99-7)		
Acute		
Other		
LD	Rabbit	35000 mg/kg
Sodium hypochlorite (CAS 7681-52-9)		
Acute		
Oral		
LD50	Mouse	5800 mg/kg
	Rat	9 g/kg
STANNOUS CHLORIDE (CAS 7772-99-8)		
Acute		
Oral		
LD50	Mouse	1200 mg/kg

Components	Species	Test Results
	Rat	700 mg/kg
Skin corrosion/irritation	May cause skin irritation.	
Serious eye damage/eye irritation	Causes serious eye irritation.	
Respiratory or skin sensitisation		
Respiratory sensitisation	Not available.	
Skin sensitisation	None known.	
Germ cell mutagenicity	For the content of kit as sold prior to reconstitution (non radioactive): No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Carcinogenicity	For the content of kit as sold prior to reconstitution (non radioactive): This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Sodium hypochlorite (CAS 7681-52-9)		3 Not classifiable as to carcinogenicity to humans.
Reproductive toxicity	For the content of kit as sold prior to reconstitution (non radioactive): Due to lack of data the classification is not possible. For UltraTag® RBC reconstituted with Sodium Pertechnetate Tc-99m: May cause harm to breastfed babies. Technetium Tc-99m is excreted in human milk during lactation, therefore, formula-feedings should be substituted for breast-feedings.	
Specific target organ toxicity - single exposure	Due to partial or complete lack of data the classification is not possible.	
Specific target organ toxicity - repeated exposure	Due to partial or complete lack of data the classification is not possible.	
Aspiration hazard	Due to partial or complete lack of data the classification is not possible.	
Chronic effects	For the content of kit as sold prior to reconstitution (non radioactive): Prolonged inhalation may be harmful.	

12. Ecological information

Ecotoxicity Harmful to aquatic life with long lasting effects.

Components	Species	Test Results
SODIUM CITRATE DIHYDRATE (CAS 6132-04-3)		
Aquatic		
Crustacea	EC50	Water flea (Ceriodaphnia dubia)
655 - 825.9 mg/l, 48 hours		
Sodium hypochlorite (CAS 7681-52-9)		
Aquatic		
Fish	LC50	Chinook salmon (Oncorhynchus tshawytscha)
0.038 - 0.065 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)

DEXTROSE , ANHYDROUS (CAS 50-99-7) -3.24

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 For the content of kit as sold prior to reconstitution (non radioactive): Dispose in accordance with all 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

TDG

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

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

15. Regulatory information

Canadian regulations This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Precursor Control Regulations

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto Protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
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	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
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

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01

List of abbreviations

TWA: Time Weighted Average Value.

Ceiling: Short Term Exposure Limit Ceiling value.

STEL: Short-Term Exposure Limit.

GHS: Globally Harmonized System of Classification and Labeling of Chemicals.

EC50: Effective Concentration 50%.

LD50: Lethal Dose, 50%.

LC50: Lethal Concentration 50%.

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