SAFETY DATA SHEET

1. Identification

Product identifier **Technescan MAG3™ Kit for the Preparation of Technetium Tc 99m Mertiatide**

Other means of identification

SDS number TMAG3

Synonyms Tc99m MAG3 * Tc99m Mertiatide * (N-[N-[N-(Mercaptoacetyl)glycyl]glycyl]-glycine benzoate (ester))

Recommended use The content of this kit as sold is non radioactive. Technescan MAG3™ is a kit for the preparation of technetium Tc 99m mertiatide, a diagnostic radiopharmaceutical. It is supplied as a sterile, nonpyrogenic, lyophilized powder. Once mixed together the content becomes radioactive. After reconstitution with sterile sodium pertechnetate Tc 99m injection, the technetium Tc 99m mertiatide (disodium[N-[N-[N-(mercaptoacetyl) glycyl]glycyl] glycinato (2-) - N,N',N",S']oxotechnetate (2-)) which is formed is suitable for intravenous administration.

Technetium Tc 99m mertiatide is a renal imaging agent for use in the diagnosis of congenital and acquired abnormalities, renal failure, urinary tract obstruction, and calculi in adults and pediatric patients. (See Pediatric Use.) It is a diagnostic aid in providing renal function, split function, renal angiograms, and renogram curves for whole kidney and renal cortex.

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Supplier

Company name Curium Canada Inc.

Address 2572 Daniel-Johnson Boulevard
Suites 217 & 220
Laval, QC H7T 2R3
Canada

Telephone number Customer Service phone number: 866-885-5988

E-mail

Emergency telephone number: 24 Hour Emergency 314-595-3700

Chemtrec 800-424-9300

2. Hazard identification

Physical hazards Not classified.

Health hazards Sensitization, skin Category 1

Label elements

Signal word Warning

Hazard statement May cause an allergic skin reaction.

Precautionary statements

Prevention Avoid breathing dust. Wear protective gloves. Contaminated work clothing should not be allowed out of the workplace.

Response IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.

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	%
SODIUM TARTRATE		868-18-8	65.4
LACTOSE		63-42-3	32.7
BETIATIDE		103725-47-9	1.6
STANNOUS CHLORIDE		7772-99-8	0.2

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 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 May cause an allergic skin reaction. Dermatitis. Rash.

The following adverse reactions have been reported: nausea, vomiting, wheezing, dyspnea, itching, rash, tachycardia, hypertension, shaking chills, fever, and seizure.

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. Wash contaminated clothing before reuse.

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 During fire, gases hazardous to health may be formed.

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. 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. Avoid breathing dust. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Provide adequate ventilation. When using, do not eat, drink or smoke. Wear protective clothing, including chemical safety goggles and chemical-resistant waterproof gloves. Wash hands and forearms after handling. Observe good industrial hygiene practices. Protect from light.

Discard after eight (8) 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.

Conditions for safe storage, including any incompatibilities

Store at controlled room temperature 20-25°C (68-77°F) both prior to and following reconstitution. Discard after eight (8) hours from the time of preparation. Store locked up. Store in original tightly closed container. Keep container tightly closed. Store in a well-ventilated place. 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. 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/m3

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

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

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

Components	Type	Value
STANNOUS CHLORIDE (CAS 7772-99-8)	15 minute	4 mg/m3
	8 hour	2 mg/m3

Biological limit values

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

Appropriate engineering controls

If engineering measures are not sufficient to maintain concentrations of dust particulates below the OEL (occupational exposure limit), suitable respiratory protection must be worn. Ventilation should be sufficient to effectively remove and prevent buildup of any dusts or fumes that may be generated during handling or thermal processing.

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. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance	Small, dry white crystals clinging to inside of 10 mL glass vial.
Physical state	Solid.
Form	Crystals.
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	Instability caused by exposure to light.
Possibility of hazardous reactions	Will not occur.

Conditions to avoid	Avoid dust formation. 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	Inhalation of dusts may cause respiratory irritation.
Skin contact	May cause an allergic skin reaction.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	May cause discomfort if swallowed.
Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation. May cause skin irritation. May cause an allergic skin reaction. Dermatitis. Rash. The following adverse reactions have been reported: nausea, vomiting, wheezing, dyspnea, itching, rash, tachycardia, hypertension, shaking chills, fever, and seizure.

Information on toxicological effects

Acute toxicity May cause an allergic skin reaction.

Components	Species	Test Results
LACTOSE (CAS 63-42-3)		
Acute		
Oral		
LD50	Rat	> 10000 mg/kg
STANNOUS CHLORIDE (CAS 7772-99-8)		
Acute		
Oral		
LD50	Mouse	1200 mg/kg
	Rat	700 mg/kg

Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.
Respiratory or skin sensitisation	
Respiratory sensitisation	Not available.
Skin sensitisation	May cause an allergic skin reaction.
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.
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 TechneScan MAG3™ 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	There are no data on the ecotoxicity of this product.
Persistence and degradability	No data is available on the degradability of any ingredients in the mixture.
Bioaccumulative potential	No data available.

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)	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

Country(s) or region	Inventory name	On inventory (yes/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

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Revision date -

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