



# SAFETY DATA SHEET

## DRAXIMAGE® MERTIATIDE

### 1. Identification

Product identifier:	<b>DRAXIMAGE® Mertiatile</b> Kit for the Preparation of Technetium Tc-99m Mertiatile Injection
Other means of identification:	Tc-99m Mertiatile; Tc-99m MAG3
Product number:	20000003518
Recommended use:	Diagnostic Medical Agent. Diagnostic radiopharmaceutical imaging agent after reconstitution with radioactive Technetium Tc-99m.
Restrictions on use:	After reconstitution with Technetium Tc-99m, this material must be handled only by trained health care professionals qualified to handle radioactive material.
Initial supplier identifier:	Jubilant DraxImage Inc., dba Jubilant Radiopharma 16751 TransCanada Highway Kirkland, Quebec, Canada, H9H 4J4 Phone: +1-514-630-7080 / 1-888-633-5343 Fax: +1-514-694-9295 / 1-866-431-4288 Hours of operation: 8am-5pm Eastern Time Web site: <a href="http://www.draximage.com">www.draximage.com</a>
Emergency telephone number (hours of operation):	1-888-633-5343 (Monday to Friday 8:00 to 17:00)

### 2. Hazard Identification

<b>Classification of the product:</b>	This is not a hazardous product under WHMIS 2015 (Hazardous Products Regulations). This product is also not subject to the Global Harmonized System GHS classification.
<b>GHS information elements</b>	
Hazard pictogram(s):	Not applicable.
Signal word:	Not applicable.
Hazard statements:	Not applicable.
<b>Precautionary statements</b>	
Prevention:	Not applicable.
Response:	Not applicable.
Storage:	Not applicable.
Disposal:	Not applicable.
<b>Other known hazards:</b>	Although some ingredients found in DRAXIMAGE® Mertiatile are skin and eye irritants, due to the small quantities present in the container, no adverse health effects are expected to occur from exposure. Read the Package Insert prior to use. Promptly remove any contamination from skin, eyes or clothing. Avoid all unnecessary exposure to the chemical substance.

### 3. Composition/Information on ingredients

Substance or mixture: Mixture

Ingredient	CAS number	Concentration
Betiatide	103725-47-9	1.6 %
Lactose	63-42-3	32.7 %
Sodium Tartrate	868-18-8	65.4 %
Stannous Chloride Dihydrate	10025-69-1	0.2 %

Within the current knowledge of the supplier and in the applicable concentration, no additional ingredient present is classified as hazardous to health or the environment and therefore do not identification in this section.

### 4. First-aid measures

Description of necessary first-aid measures

Inhalation:	Remove the patient to open air, far from the contaminated premises. Get medical advice if you feel unwell.
Ingestion:	Not expected to require first-aid measures. Get medical advice if you feel unwell.
Skin contact:	Wash skin with water and soap. Seek medical advice if irritation develops.
Eye contact:	Wash immediately with running water for at least 15 minutes and seek medical advice if irritation develops.

Most important symptoms and effects, whether acute or delayed

Under normal use conditions, this product is not expected to cause adverse health effects.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician:	Treat symptomatically.
Specific treatments:	No specific treatment.

### 5. Fire-fighting measures

Suitable extinguishing media:	This product is not combustible. In case of fire in the surroundings: use appropriate extinguishing media.
Unsuitable extinguishing media:	None in particular.
Specific hazards arising from the hazardous product:	None known.
Hazardous combustion products:	When heated to decomposition, substance may emit oxides of carbon and corrosive fumes of hydrochloric acid.
Special protective equipment and precautions for fire-fighters:	Wear NIOSH approved self-contained breathing apparatus with full face piece and full protective clothing.

### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Restrict access to area until completion of cleanup.

For emergency responders: Wear adequate personal protective equipment.

Methods and materials for containment and cleaning up

Accidental release: Collect non-radioactive spills and dispose of material as non-hazardous waste.  
**For Mertiatide Reconstituted with Sodium Pertechnetate Tc-99m:** If any loss or release of the radioactive contents occurs, notify your Radiation Safety Officer. All cleanup operations should be performed according to the Standard Operating Procedures (SOP) for radiation protection established for your facility and by the CNSC, NRC, or other applicable local, provincial, state or federal regulations.

Refer to the Canadian Nuclear Safety Commission Radiation Radionuclide Information Booklet at [http://www.nuclearsafety.gc.ca/pubs\\_catalogue/uploads/Radionuclide-Information-Booklet-2018-eng.pdf](http://www.nuclearsafety.gc.ca/pubs_catalogue/uploads/Radionuclide-Information-Booklet-2018-eng.pdf) for information on Tc-99m.

## 7. Handling and storage

Precautions for safe handling: Use appropriate personal protective equipment. **For Mertiatide Reconstituted with Sodium Pertechnetate Tc-99m:** Handling devices such as syringe shields and tongs should be used.

Advice on general hygiene: Eating, drinking and smoking in working areas should be prohibited. Wash hands with soap and water before meals and at the end of the work shift. Remove contaminated clothing and protective equipment before entering eating areas.

Conditions for safe storage, including any incompatibilities: Store at controlled room temperature, 20°C to 25°C (68°F to 77°F), and protected from light before the reconstitution with sodium pertechnetate Tc-99m. Refer to the Package Insert and product labeling for specific approved storage temperature ranges.  
**For Mertiatide Reconstituted with Sodium Pertechnetate Tc-99m:** the product should be shielded and stored at or below room temperature. Storage and disposal of the reconstituted radioactive product should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorised to license the use of this radionuclide.

## 8. Exposure controls/Personal protection

Control parameters:

Ingredient	CAS Number	Value	Control Parameters	Basis
Stannous Chloride Dihydrate	10025-69-1	TWA	2 mg/m <sup>3</sup> , as Sn	OSHA - Permissible Exposure Limit (PEL) ACGIH® - Threshold Limit Value (TLV®)

Appropriate engineering controls: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual protection measures

Hand protection: Wear protective gloves.

Eye protection: Wear safety glasses with side shields.

Respiratory protection: None required under normal conditions of use and storage.

Skin and body protection: Wear clean body-covering clothing.

## 9. Physical and chemical properties

Appearance: Small, dry, white plug or crystals clinging to the inside of a 10 mL colorless glass vial.

Odour: Odourless

Odour threshold:	Not applicable
pH:	Not available
Melting point:	ca. 0 °C (32 °F) reconstituted
Freezing point:	ca. 0 °C (32 °F) reconstituted
Initial boiling point and boiling range:	ca. 100 °C (212 °F) reconstituted
Flash point:	Not applicable
Evaporation rate:	Not available
Upper and lower flammability or explosive limits:	Not applicable
Vapour pressure:	Not available
Vapour density:	Not available
Relative density:	Not available
Solubility:	Soluble in water
Partition coefficient — n-octanol/water:	Not available
Auto-ignition temperature:	Not applicable
Decomposition temperature:	Not available
Viscosity:	Not available

## 10. Stability and reactivity

Reactivity:	Not applicable.
Chemical stability:	Under recommended conditions of use and storage, the product is stable.
Possibility of hazardous reactions:	Under normal conditions of use and storage, hazardous reactions will not occur
Conditions to avoid:	None under recommended conditions of use and storage
Incompatible materials:	None reasonably foreseeable.
Hazardous decomposition products:	When heated to decomposition, substance may emit oxides of carbon and corrosive fumes of hydrochloric acid.

## 11. Toxicological information

The product is contained within a hermetically sealed glass serum vial and direct exposure is not likely to occur under normal handling and using the precautions described. Unusual events may lead to exposure through skin or eye contact. The information below pertains to the individual ingredients found in this product.

### Acute toxicity:

Stannous Chloride Dihydrate	LD <sub>50</sub> Oral (rat): 700 mg/kg LD <sub>50</sub> Intravenous (rat): 7830 mg/kg
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**Information on the likely routes of exposure:** Dermal contact. Eye contact.

### Symptoms related to the physical, chemical and toxicological characteristics

Under normal use conditions, this product is not expected to cause adverse health effects.

### Delayed and immediate effects, and chronic effects from short-term and long-term exposure:

**Teratogenicity** (Stannous Chloride Dihydrate): Species: rat; dose: 3 mg/kg; route of application: oral; exposure time: 7-12 days pregnant Result: Specific developmental abnormalities: craniofacial (including nose and tongue).

**Mutagenicity** (Stannous Chloride Dihydrate): Species: human; dose: 10 µmol/l; cell type: leukocyte



# DRAXIMAGE® MERTIATIDE

Mutation test: DNA damage

Species: hamster; dose: 50 µmol/l; cell Type: ovary

Mutation test: DNA damage

**Reproductive and Developmental Toxicity** (Stannous Chloride Dihydrate):

Species: rat; dose: 3 mg/kg; route of application: oral; exposure time: 7-12 days pregnant Effects on Embryo or Fetus: Fetal death.

Effects on Fertility: Post-implantation mortality (e.g., dead and/or resorbed implants per total number of implants).

**Carcinogenicity:** No long term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m Mertiatile Injection affects fertility in males or females.

None of the components present in this material at concentrations equal to or greater than 0.1 % are listed by IARC, NTP, OSHA, or ACGIH® as a carcinogen. When this kit is reconstituted with radioactive material, this product contains a substance known to the State of California to cause cancer.

## 12. Ecological information

Considering this product is intended for use by hospital or clinic patients, it is expected to be treated by standard wastewater treatment facilities with no adverse environmental impacts.

## 13. Disposal considerations

Disposal methods:

Mertiatile reconstituted with Sodium Per technetate Tc-99m 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, CNSC, and any 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 radioactive or a Biohazard, Mertiatile is considered non-hazardous. Consult local, provincial, state, or federal regulations for proper disposal.

## 14. Transport information

**International Air Transport Association (IATA/ICAO):** This product is not dangerous under current provisions of the regulation.

**Department of Transportation Regulations (DOT):** This product is not regulated in the non-radioactive form.

## 15. Regulatory information

**CERCLA Reportable Quantities:**

When this kit is reconstituted with radioactive material, the Reportable Quantity for Tc-99m = 100 Ci (3.7 TBq) Releases to air, land or water of these hazardous substances which exceed the Reportable Quantity (RQ) must be reported.

SARA Title III

302 Extremely Hazardous Substances: None

311/312 Hazard Categories: None

313 Toxic substances subject to annual release reporting requirements: None.

RCRA Hazardous Waste Status

Non-hazardous (See Section 13 for additional details.)

California Proposition 65 Warning

When this kit is reconstituted with radioactive material, this product contains a substance known to the State of California to cause cancer.

Australian Hazchem Code: None allocated.

Australian Poison Schedule: None allocated.

NFPA Ratings: Health: 0 Flammability: 0 Reactivity: 0

WHMIS: This Safety Data Sheet (SDS) has been prepared according to the Workplace Hazardous Materials Information Systems (2015) requirements of the Hazardous Products Regulations (HPR) and the SDS contains all of the information required by the HPR.

## 16. Other information

### SDS information

Version:	1
Date (dd/mm/yyyy):	12/11/2020
Prepared by:	CFT Canada

This document pertains, in most part, to the non-radioactive, non-reconstituted, lyophilized product. Once reconstituted with radioactive Tc-99m, the material falls under the regulation of the CNSC, NRC, or other local, provincial, state, or federal agencies. Only trained professionals in licensed facilities are permitted to handle the radioactive reconstituted product.

Refer to the Canadian Nuclear Safety Commission Radiation Radionuclide Information Booklet at [http://www.nuclearsafety.gc.ca/pubs\\_catalogue/uploads/Radionuclide-Information-Booklet-2018-eng.pdf](http://www.nuclearsafety.gc.ca/pubs_catalogue/uploads/Radionuclide-Information-Booklet-2018-eng.pdf) for information on Tc-99m.

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