



**MATERIAL SAFETY DATA SHEET
DRAXIMAGE® Gluceptate**

Kit for the Preparation of Technetium Tc99m Gluceptate Injection

SECTION 1. CHEMICAL PRODUCT & COMPANY IDENTIFICATION

Product Name: DRAXIMAGE® Gluceptate Kit
Product Number: 500220
Synonyms: Tc-99m Gluceptate; Tc-99m Glucoheptonate
Category: Diagnostic Medical Agent

Manufactured for: DRAXIMAGE, a division of DRAXIS Specialty Pharmaceuticals Inc.
A Jubilant Organosys Company
16751 TransCanada Hwy.
Kirkland, QC, H9H 4J4
CANUTEC:
Information Tel. No.: (514) 630-7080
1-888-633-5343
(613) 996-6666

SECTION 2. COMPOSITION, INFORMATION ON INGREDIENTS

Chemical Ingredients:

<u>Component (quantity per vial)</u>		<u>CAS #</u>	<u>Wt %</u>
Glucoheptonic Acid	50 mg	29037-00-7	98 %
Stannous Chloride Dihydrate	1 mg	10025-69-1	2 %

SECTION 3. HEALTH HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Read Package Insert prior to use. Promptly remove any contamination from skin, eyes or clothing. Avoid all unnecessary exposure to the chemical substance.

POTENTIAL HEALTH EFFECTS

The hazardous ingredients found in DRAXIMAGE® GLUCEPTATE are skin and eye irritants, but due to the small quantities present in the container, no adverse health effects are expected to occur from exposure.

Skin Contact:

Not expected to be a health hazard.

Eye Contact:

Not expected to be a health hazard.

Chronic Exposure:

Not expected to be a health hazard.

Inhalation:

Not expected to be a health hazard.

Aggravation of Pre-existing Conditions:

No information found.

Ingestion:

Not expected to be a health hazard.

CARCINOGENICITY

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.

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SECTION 4. FIRST AID MEASURES

Inhalation:

Not expected to require first aid measure; remove to fresh air, support breathing by usual methods if necessary.

Ingestion:

Not expected to require first aid measure; call physician if necessary.

Skin Exposure:

Wash exposed area with soap and water. Get medical advice if irritation develops.

Eye Exposure:

Wash thoroughly with running water for at least 15 minutes. Get medical advice if irritation develops.

SECTION 5. FIRE FIGHTING MEASURES

Fire: Not considered to be a fire hazard.

Explosion: Not considered to be an explosion hazard.

Fire Extinguishing Media: Use media suitable for extinguishing surrounding fire.

Special Instructions: In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Collect non-radioactive spills and dispose of material as non-hazardous waste.

For GLUCEPTATE Reconstituted with Sodium Pertechnetate Tc-99m: If any loss or release of the radioactive contents occur, notify your Radiation Safety Officer. All cleanup operations should be performed according to the Standard Operating Procedures (SOP's) 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 Safety Data Sheet for Tc-99m at <http://www.cnsccsn.gc.ca/eng/pdfs/Tc-99m.pdf>

SECTION 7. HANDLING AND STORAGE

The drug should be stored at 2 °C to 25 °C prior to reconstitution with Sodium Pertechnetate Tc-99m. After reconstitution, the shielded vial should be stored at 2 °C to 8 °C and discarded after eight (8) hours from the time of preparation. Handling devices such as syringe shields and tongs should be used. 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.

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SECTION 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

Airborne Exposure Limits:

For Tin Compounds:

-OSHA Permissible Exposure Limit (PEL)

2 mg/m³ (TWA), as Sn

-ACGIH Threshold Limit Value (TLV)

2 mg/m³ (TWA), as Sn

Engineering Controls:

Not expected to require any special ventilation.

Respiratory Protection:

Not expected to require personal respirator usage

Skin Protection:

Wear protective gloves and clean body-covering clothing.

Eye/Face Protection:

Safety glasses

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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

Boiling Point: ca. 100 °C (212 °F) reconstituted.

Odour: Odourless.

Melting Point: ca. 0 °C (32 °F) reconstituted

Solubility: Soluble in water.

SECTION 10. STABILITY AND REACTIVITY

Stability: Stable under ordinary conditions of use and storage.

Hazardous Polymerisation: Will not occur

Hazardous Decomposition Products:

When heated to decomposition, substance may emit oxides of carbon and corrosive fumes of hydrochloric acid.

Incompatibilities with other Materials: None reasonably foreseeable.

SECTION 11. TOXICOLOGICAL INFORMATION

For detailed toxicological information on specific components, write to the address listed in Section 1 – Attn: Regulatory Affairs Department.

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SECTION 12. ECOLOGICAL INFORMATION

Because 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.

SECTION 13. DISPOSAL CONSIDERATIONS

GLUCEPTATE reconstituted with Sodium Pertechnetate Tc-99m is Radioactive Waste until the activity has decayed to nondetectable levels. Radioactive waste must be handled in accordance with procedures established by your Radiation Safety Officer, NRC, CNSC, 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 radioactive or a Biohazard, GLUCEPTATE is considered non-hazardous. Consult local, provincial, state, or federal regulations for proper disposal.

SECTION 14. TRANSPORTATION INFORMATION

DOT (Department of Transportation): Not regulated in the non-radioactive form.

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantities:

Tc-99m = 100 Ci (3.7 E 12 Bq)

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.

WHMIS: This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

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SECTION 16. OTHER INFORMATION

MSDS Status: Revised February 04, 2010

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

Product Use: Diagnostic imaging agent

Revision Information: Rev. 3. Periodic review with minor updates in format and content.

This document pertains, in most part, to the non-radioactive, non-reconstituted, lyophilized product. Once reconstituted with radioactive ^{99m}Tc , 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 (CNSC) Radiation Safety Data Sheet (RSDS) for Tc-99m at <http://www.cnscccsn.gc.ca/eng/pdfs/Tc-99m.pdf>

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