Safety Data Sheet

1. IDENTIFICATION

Product Name:	**DRAXIMAGE® DTPA** Kit for the Preparation of Technetium Tc 99m Pentetate Injection
Product Number:	500170, 500520
Recommended Use:	Diagnostic Medical Agent. Diagnostic radiopharmaceutical imaging agent after reconstitution with radioactive Technetium Tc 99m.
Restrictions for Use:	After reconstitution with Technetium Tc 99m, this material must be handled only by trained health care professionals qualified to handle radioactive material.
Manufacturer:	Jubilant DraxImage Inc. 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: www.draximage.com
Synonyms:	Tc 99m Pentetate, Tc 99m DTPA

2. HAZARD IDENTIFICATION

Classification / Category: Does not present hazards within the WHMIS/GHS list of physical Hazard Classes.
Health Hazards: Not expected to be a health hazard as per the WHMIS/GHS list of Health Hazards. Although some ingredients found in DRAXIMAGE® DTPA are skin and eye irritants, due to the small quantities present in the container, no adverse health effects are expected to occur from exposure.
Label Elements:
Symbol: Not applicable
Signal Word: Not applicable
Precautions:
Read the Package Insert prior to use.
Promptly remove any contamination from skin, eyes or clothing. Avoid all unnecessary exposure to the chemical substance.
Eye contact: Not expected to be a health hazard.
Skin contact: Not expected to be a health hazard.
Inhalation: Not expected to be a health hazard.
Ingestion: Not expected to be a health hazard.
Chronic exposure: Not expected to be a health hazard.
Aggravation of pre-existing Conditions: No information found.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Ingredients Component (quantity per vial):		CAS #	Wt %
Pentetic Acid	(20 mg)	67-43-6	69 %
p-Aminobenzoic Acid	(5 mg)	150-13-0	17.3 %
Calcium Chloride Dihydrate	(3.73 mg)	10035-04-8	12.8 %
Stannous Chloride Dihydrate	(0.25 mg)	10025-69-1	0.9 %

4. First-Aid Measures

Eye Exposure: Wash thoroughly with running water for at least 15 minutes. Get medical advice if irritation develops.
Skin Exposure: Wash exposed area with soap and water. Get medical advice if irritation develops.
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.
Most Important Symptoms and Effects, Acute and Delayed: Not applicable
Immediate Medical Attention and Special Treatment: Not applicable

5. Fire Fighting Measures

Fire Extinguishing Media: Use media suitable for extinguishing surrounding fire.
Specific Hazards Arising from the Product: None
Special Instructions: There are no specific fire fighting instructions relative to this product. 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.

6. Accidental Release Measures

Collect non-radioactive spills and dispose of material as non-hazardous waste.
For DTPA 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 Radionuclide Information Booklet at http://www.nuclearsafety.gc.ca/pubs_catalogue/uploads/Radionuclide-Information-Booklet-2016-eng.pdf for information on Tc-99m.

7. Handling and Storage

There are no specific safety-related requirements for storage however the drug should be stored at or below room temperature before reconstitution with sodium pertechnetate Tc-99m. Do not freeze. Refer to the Package Insert and product labelling for specific approved storage temperature ranges.
For DTPA Reconstituted with Sodium Pertechnetate Tc-99m, the radioactive vial should be shielded and stored at or below room temperature. Do not freeze. Refer to the Product Insert and product labelling for specific approved storage temperature ranges
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.

8. Exposure Controls/Personal Protection

For Tin Compounds:

Airborne Exposure Limits		OSHA Permissible Exposure Limit (PEL)	ACGIH ® Threshold Limit Value (TLV®)
Stannous Chloride Dihydrate	(0.25 mg/vial)	2 mg/m^3 (TWA), as Sn	2 mg/m^3 (TWA), as Sn

TWA = Time Weighted Average
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.

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: Neutral when reconstituted
Melting point: ca. 0 ºC (32 ºF) reconstituted
Freezing point: ca. 0 ºC (32 ºF) reconstituted
Initial Boiling point and boiling range: ca. 100 ºC (212 ºF) reconstituted
Flash Point: Not applicable
Evaporation rate: Not applicable,
Solubility: Soluble in water

10. STABILITY AND REACTIVITY

Reactivity: Not applicable
Chemical Stability: Stable under recommended conditions of use and storage.
Possibility of Hazardous Reactions: None reasonably foreseeable.
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 an 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.

Stannous Chloride Dihydrate (0.25 mg/vial)

Acute Toxicity:
Oral Data
LD50: 700 mg/kg (rat)
Intravenous Data
LD50: 7830 mg/kg (rat)
Teratogenicity: 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: Species: human; dose: 10 µmol/l; cell type: leukocyte
Mutation test: DNA damage
Species: hamster; dose: 50 µmol/l; cell Type: ovary
Mutation test: DNA damage
Reproductive and Developmental Toxicity:
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).

Pentetic Acid (20 mg/vial)

Acute Toxicity:
Oral Data
LD50: >2000 mg/kg (rat)

Teratogenicity: no abnormalities observed in the rat
Mutagenicity: no data available
Reproductive and Developmental Toxicity: no data available

p-aminobenzoic acid (5 mg/vial)

Acute Toxicity:
Oral Data
LD50: 6000 mg/kg (rat)
LD50: 2850mg/kg (mouse)
LD50: 1000 mg/kg (dog)
LD50: 1830mg/kg (rabbit)

Calcium Chloride Dihydrate (3.73 mg/vial)

Acute Toxicity:
Oral Data
LD50: 1000 mg/kg (rat)

Carcinogenicity: No long term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m DTPA 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

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.

13. DISPOSAL CONSIDERATIONS

DTPA reconstituted with Sodium Pertechnetate 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, DTPA is considered non-hazardous. Consult local, provincial, state, or federal regulations for proper disposal.

14. TRANSPORTATION INFORMATION

U.S. Department of Transportation Regulations (DOT): Not regulated in the non-radioactive form.
International Air Transport Association (IATA): This product does not meet the definition of dangerous goods, and is therefore exempt from IATA/ICAO regulations.

15. REGULATORY INFORMATION

CERCLA Reportable Quantities:
When this kit is reconstituted with radioactive material, the Reportable Quantity for 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.
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

Revision Information: Rev. 4, February 01, 2017

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 Radiation Radionuclide Information Booklet at http://www.nuclearsafety.gc.ca/pubs_catalogue/uploads/Radionuclide-Information-Booklet-2016-eng.pdf for information on Tc-99m.

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