MATERIAL SAFETY DATA SHEET

DRAXIMAGE® Sestamibi
Kit for the preparation of Technetium Tc 99m Sestamibi Injection

Date Published: October 4th, 2006
Date Revised: July 2011
Revision No.: 2

Section 1: Product and Company Identification

Product Name: DRAXIMAGE® Sestamibi

Manufacturer:
Jubilant DraxImage Inc.
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Synonyms and Tradenames: Sestamibi kit; Tc-99m Sestamibi; Cardiolite® kit; Miraluma® kit; Kit for the preparation of Technetium Tc 99m Sestamibi for Injection

Category: Diagnostic Imaging Agent

Product Code: 500141 / 500163 / 500450

Section 2: Hazards Identification

NFPA Rating:

Health : 2
Flammability : 0
Reactivity : 0

NPCA-HMIS Rating:

Health : 2
Flammability : 0
Reactivity : 0

Emergency Overview: White powder. Toxic by ingestion. May cause an allergic/asthmatic reaction. May cause skin and eye irritation. May cause central nervous system, cardiovascular, and gastrointestinal effects. No information is available on the environmental effects.

Potential Acute Health Effects:

For the kit non-reconstituted:

Skin & Eyes Contact: Mannitol, sodium citrate dihydrate, and L-cysteine hydrochloride monohydrate may contribute to the potential for the lyophilized product to cause skin and eye irritation.

Inhalation: Not established.

Ingestion: Not established.

For the kit post-reconstitution: Data are provided for DRAXIMAGE® Sestamibi kit after reconstitution with sodium pertechnetate Tc-99m.

Adverse reactions from clinical administration of DRAXIMAGE® Sestamibi following reconstitution with Sodium Pertechnetate Tc-99m include headache, nausea, angina, chest pain, and alterations of taste and smell. Additional less common signs include transient arthritis, angioedema, cardiac arrhythmia, dizziness, fainting and gastrointestinal effects, such as abdominal pain and vomiting. Allergic hypersensitivity reactions have been observed.

Sodium pertechnetate Tc-99m is excreted in human milk during lactation. It is not known whether Technetium Tc-99m Sestamibi is excreted in human milk.

Potential Chronic Health Effects:

Carcinogenic Effects: 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.

Reproductive Toxicity: Not established.

Medical Condition Aggravated by Exposure: No information available.

Section 3: Composition / Information on Ingredients

Chemical Ingredients	Quantity/vial	CAS No	Percent	Hazardous
Tetrakis (2-methoxyisobutylisonitrile) copper(I) tetrafluoroborate	1 mg	103694-84-4	4.1	Yes
Sodium citrate dihydrate	2.6 mg	6132-04-3	10.5	Yes
L-cysteine hydrochloride monohydrate	1 mg	52-89-1	4.1	Yes
Mannitol	20 mg	69-65-8	81.1	Yes
Stannous Chloride Dihydrate	0.075 mg	10025-69-1	0.3	Yes

Section 4: First Aid Measures

Eyes Contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.

Skin Contact: Flush skin with water after contact. Wash contaminated clothing before reuse.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

Ingestion: If swallowed, immediately give 2 glasses of water and induce vomiting. Never give anything by mouth to an unconscious person. Call a physician.

Notes to Physicians: DRAXIMAGE® Sestamibi, Kit for the Preparation of Technetium Tc 99m Sestamibi for Injection, is a myocardial perfusion agent used to detect coronary artery disease.
In case of overexposure, treatment should be symptomatic and supportive. No specific antidote for overexposure has been identified.

If ingested and patient is conscious, induction of emesis may be indicated. Gastric lavage may be indicated if the patient is unconscious. Activated charcoal slurry may be used. To prepare,

suspend 50 grams of activated charcoal in 400 mL of water in a plastic bottle and shake well. Orally administer 5 mL/kg or 350 mL for an average adult (70 kg or 154 lbs).

Section 5: Fire Fighting Measures

Flammability: Not expected to be a fire hazard.

Autoignition Temperature: Not available.

Flash point: Not applicable.

Explosion Hazards: Not expected to be an explosion hazard.

Extinguishing Media: Water spray, foam, dry chemical, CO_2.

Fire Fighting: Keep personnel removed and upwind from fire. Wear self-contained breathing apparatus. Wear full protective equipment.

Section 6: Accidental Release Measures

Procedure(s) of Personal Precaution(s): Review Fire Fighting Measures in Section 5, Handling and Storage in Section 7, and use appropriate Personal Protective Equipment as indicated in Exposure Controls / Personal Protection Section 8 before and during clean-up.

Methods for Cleaning up: To collect non-radioactive spills, use HEPA filtered vacuum or wet mop. Do not generate dust. Dispose of material as non-hazardous waste.

Accidental Release Measures: If reconstituted with Technetium Tc-99m, notify your site Radiation Safety Officer for proper disposal procedures.

Section 7: Handling and Storage

Handling: Do not generate dust.

User Exposure: Do not breathe dust. Do not get in eyes, on skin or clothing. Wash thoroughly after handling. Wash clothing after use.

Storage: The drug should be stored at 2 ºC to 25 ºC (35.6 °F to 77 °F) prior to reconstitution with Sodium Pertechnetate Tc-99m. After reconstitution, the shielded vial should be stored at 15 ºC to 25 ºC (59 °F to 77 °F) and discarded after six (6) 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.

Section 8: Exposure Controls / Personal Protection

Exposure Limits:

For Tin Compounds:

OSHA Permissible Exposure Limit (**PEL**): 2 mg/m^3 (TWA), as Sn
ACGIH Threshold Limit Value (**TLV**): 2 mg/m^3 (TWA), as Sn

For ^{99m}Tc:

NRC Occupational concentration limit is 6×10^{-5} μCi/mL of air.

Engineering Controls: Not expected to require any special ventilation.

Personal Protective Equipment:

Eye/Face: Safety goggles or safety glasses.

Respiratory: Not expected to require personal respirator usage. Wear NIOSH/MSHA-approved (or equivalent) respirator where a respirator is judged appropriate to prevent inhalation. Consult the site safety professional for additional guidance, as needed.

Skin: Wear protective gloves and clean body covering clothing. Consult the site safety professional for additional guidance, as needed.

Section 9: Physical and Chemical Properties

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

Odor: Slight garlic-like

Boiling Point: ca. 100 ºC (212 ºF) reconstituted.

Melting Point: ca. 0 ºC (32 ºF) reconstituted

Solubility: Soluble in water (25 mg/mL).

pH: 5.0-6.0 after reconstitution

DRAXIMAGE® Sestamibi is supplied as a 10 mL vial, sterile and non-pyrogenic. The content of the vial is lyophilized and stored under nitrogen.

Section 10: Stability and Reactivity

Chemical Stability: Stable under ordinary conditions of use and storage.

Incompatibility with Other Materials: Mannitol is incompatible with strong oxidizers, including halogen, isocyanates and metal alkalies.

Decomposition: Thermal decomposition may produce CO_2, CO, NO_2 or corrosive fumes of hydrochloric acid.

Hazardous Polymerisation: Will not occur.

Section 11: Toxicological Information

Route of Exposure:
Eyes Contact: not established.
Skin Contact: not established.
Inhalation: not established.
Oral Route: not established.

Toxicity Data: Data on the active component tetrakis (2-methoxyisobutylisonitrile)copper(I) tetrafluoroborate ($[Cu(MIBI)_4]BF_4$) are presented. Data are also presented for mannitol, sodium citrate dihydrate and L-cysteine hydrochloride monohydrate.

Tetrakis (2-methoxyisobutylisonitrile)copper(I) tetrafluoroborate

Acute Toxicity:
Ocular Data
Mild eye irritant in animals.

Oral Data
LD50: 80 mg/kg (mouse)
LD50: 123 mg/kg (rat)

Intravenous Data
LD50: 8 mg/kg (rat)
LD50: 10 mg/kg (dog)
LD50: 12 mg/kg (mouse)
LDLo: 7 mg/kg (rat)

Clinical signs of overdose in mice were dyspepsia, diarrhea, hypoactivity, hypothermia, anorexia, ataxis and tremors.

Mutagenicity: Tetrakis (2-methoxyisobutylisonitrile)copper(I) tetrafluoroborate was not genotoxic in "*in vitro*" Ames, Chinese Hamster Ovary, sister chromatid exchange and "*in vivo*" mouse micronucleus assays. It did cause chromosomal aberrations in an "*in vitro*" human lymphocyte assay at cytotoxic concentrations.

Sodium Citrate Dihydrate

Acute Toxicity:
Intravenous Data
LD50: 71 mg/kg (mouse)
LD50: 418 mg/kg (rabbit)

Subcutaneous Data
LD50: 2580 mg/kg (mouse)

Reproductive and Developmental Toxicity: Sodium citrate was not teratogenic in rats.

L-Cysteine Hydrochloride Monohydrate

Acute Toxicity:
Ocular Data
Not an irritant in animals (3 % near-neutral solution)

Oral Data
LD50: 660 mg/kg (mouse)
LD50: 1890 mg/kg (rat)

Reproductive and Developmental Toxicity: L-Cysteine hydrochloride monohydrate was not teratogenic in rats and mice.

Mannitol

Acute Toxicity:
Oral Data
LD50: 13500 mg/kg (rat)
LD50: 22000 mg/kg (mouse)

Intravenous Data
LD50: 9690 mg/kg (rat)
LD50: 7470 mg/kg (mouse)
Reproductive/Developmental Toxicity: Mannitol was not a teratogen or reproductive toxin in mice, rats, and rabbits at doses up to 1600 mg/kg.

Mutagenicity: Mannitol was not genotoxic in a series of "in vitro" and "in vivo" assays.

Carcinogenicity: In an early study of 1, 5, or 10 percent mannitol, given for 94 weeks in the diet of Wistar rats, a low incidence of benign thymic tumors occurred in females, which was apparently treatment-related. A subsequent life-study at similar dose levels in Sprague-Dawley, Fischer, and Wistar rats revealed no carcinogenic effect in the thymus. In a 103-week mouse feeding study, mannitol administered up to 5 % caused no statistically significant increases in tumor incidence.

Stannous Chloride Dihydrate

Acute Toxicity:
Oral Data
LD50: 700 mg/kg (rat)

Intravenous Data
LD50: 7830 µg/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).

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.

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation: Not available.

Toxicity of the Products of Biodegradation: No information available.

Special Remarks on the Products of Biodegradation: No information available.

Section 13: Disposal Considerations

Waste Disposal: If not radioactive, DRAXIMAGE® Sestamibi is considered non-hazardous. Consult local, provincial, state, or federal regulations for proper disposal.

DRAXIMAGE® Sestamibi reconstituted with Sodium Pertechnetate Tc-99m must be disposed in 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 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.

Section 14: Transport 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.

Section 15: Regulatory Information

United States Regulatory Information:
CERCLA Reportable Quantities: Tc-99m = 100 Ci (3.7×10^{12} Bq)
Releases to air, land or water of these hazardous substances which exceed the Reportable Quantity (RQ) must be reported to the National Response Center at 800-424-8802.
SARA listed: No
TSCA Inventory Item: None

Canadian Regulatory Information:
WHMIS Classification: This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR), and the MSDS contains all the information required by the CPR.
DSL: No
NDSL: No

Section 16: Other Information

References
Information from Bristol-Myers Squibb MSDS for Cardiolite® Kit, March, 2002.
Information from Sigma-Aldrich MSDS for Stannous Chloride Dihydrate, April, 2006.

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.

The data in this Material Safety Data Sheet relates only to the specific material designated herein and does not relate to use in combination with any other material or in any process.

This information is based upon technical information believed to be reliable. It is subject to revision as additional knowledge and experience is gained.
Date Published: October 4th, 2006
Date Revised: July 2011
Revision No.: 2

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