



Safety Data Sheet

1. IDENTIFICATION

Product Name: DRAXIMAGE® Sestamibi
Kit for the Preparation of Technetium Tc99m Sestamibi Injection

Product Number: 500141, 500163, 500450

Recommended Use: Diagnostic Medical Agent. Diagnostic radiopharmaceutical imaging agent after reconstitution with radioactive Technetium Tc99m.

Restrictions for Use: After reconstitution with Technetium Tc99m, this material must be handled only by trained health care professionals qualified to handle radioactive material.

Manufacturer: Jubilant DraxImage Inc.
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Web site: www.draximage.com

Synonyms: Sestamibi kit; Tc-99m Sestamibi; Cardiolite® kit; Miraluma® kit;
Kit for the preparation of Technetium Tc 99m Sestamibi for Injection

2. HAZARD IDENTIFICATION

Classification / Category: Does not present hazards within the WHMIS/GHS list of Physical Hazard Classes.

NFPA Rating:

Health : 2
Flammability : 0
Reactivity : 0

NPCA-HMIS Rating:

Health : 2
Flammability : 0
Reactivity : 0

Health Hazards:

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.

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.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Ingredients Component (quantity per vial):	Quantity per vial	CAS #	Wt %
Tetrakis (2-methoxyisobutylisonitrile) copper(I) tetrafluoroborate	1 mg	103694-84-4	4.1
Sodium citrate dihydrate	2.6 mg	6132-04-3	10.5
L-cysteine hydrochloride monohydrate	1 mg	52-89-1	401
Mannitol	20 mg	69-65-8	81.1
Stannous Chloride Dihydrate	0.075 mg	10025-69-1	0.3

4. FIRST-AID MEASURES

Eye Exposure: In case of contact, wash thoroughly with running water for at least 15 minutes. Call a physician.

Skin Exposure: Flush exposed area 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 inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

Immediate Medical Attention and Special Treatment: 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).

Most Important Symptoms and Effects, Acute and Delayed: 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

For Sestamibi before reconstitution: To collect non-radioactive spills, use HEPA filtered vacuum or wet mop. Do not generate dust. Dispose of material as non-hazardous waste.

For Sestamibi 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

Handling: Do not generate product dust. Do not breathe dust. Do not get in eyes, on skin or clothing. Wash thoroughly after handling. Wash clothing after use.

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 allow the product to freeze. Refer to the package insert for specific permissible storage temperatures.

For SESTAMIBI reconstituted with Sodium Pertechnetate Tc-99m, the shielded vial should be stored at or below room temperature but do not freeze. Refer to the package insert for specific approved storage temperatures after reconstitution. 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 (0.1 mg/vial)	2 mg/m ³ (TWA), as Sn	2 mg/m ³ (TWA), as Sn

TWA = Time Weighted Average

For Tc-99m: NRC occupational concentration limit is 6 x 10E-3 µCi/mL of air.

Engineering Controls: Not expected to require any special ventilation.

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

Eye/Face Protection: Safety glasses or safety goggles.

9. PHYSICAL AND CHEMICAL PROPERTIES

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

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

Odour: Slight garlic-like.

Odour threshold: Not applicable

pH: 5.0 – 6.0 after reconstitution

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 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

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]BF₄) 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 tumours 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 tumour incidence.

Stannous Chloride Dihydrate

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).

Carcinogenicity: When this kit is reconstituted with Sodium Pertechnetate Tc-99m, 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

DRAXIMAGE® SESTAMIBI 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.

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

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 1-800-424-8802.

SARA listed: No

TSCA Inventory Item: None

Canadian Regulatory Information:

DSL: No

NDSL: No

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. 3, February 01, 2017

References

Information from Lantheus SDS for Cardiolite® Kit, November, 2015.

Information from Sigma-Aldrich SDS for Stannous Chloride Dihydrate, March, 2015

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 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.

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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