

Bristol-Myers Squibb Company  
MATERIAL SAFETY DATA SHEET

CARDIOLITE

Revised 14-SEP-2006

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CHEMICAL PRODUCT/COMPANY IDENTIFICATION  
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Material Identification

CARDIOLITE is a registered trademark of:  
Bristol-Myers Squibb Medical Imaging, Inc.

Grade : CLINICAL

Tradenames and Synonyms

CARDIOLITE KIT  
Tc99m SESTAMIBI  
TETRAKIS(2-METHOXY ISOBUTYL ISONITRILE) COPPER (I)  
...TETRAFLUOROBORATE  
MIRALUMA KIT  
KIT FOR THE PREPARATION OF TECHNETIUM Tc99m SESTAMIBI FOR  
...INJECTION

Company Identification

MANUFACTURER/DISTRIBUTOR  
Bristol-Myers Squibb Medical Imaging, Inc.  
331 Treble Cove Road  
Billerica, MA 01862

EMERGENCY CONTACT

CHEMTREC (800) 424-9300. For all  
international transportation emergencies call CHEMTREC  
at 703-527-3887, collect calls accepted.

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COMPOSITION/INFORMATION ON INGREDIENTS  
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Components

Material	CAS Number	%
MANNITOL	69-65-8	80.0
SODIUM CITRATE DIHYDRATE	68-04-2	10
TETRAKIS (2-METHOXY ISOBUTYL ISONITRILE) COPPER (I) TETRAFLUOROBORATE	103694-84-4	4
L-CYSTEINE HYDROCHLORIDE MONOHYDRATE	52-89-1	4

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HAZARDS IDENTIFICATION  
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Emergency Overview

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

Potential Health Effects

Data are provided for CARDIOLITE after reconstitution  
with Sodium Pertechnetate Tc99m. Data are also provided for  
mannitol, sodium citrate dihydrate, and Lcysteine  
hydrochloride monohydrate.

Bristol-Myers Squibb Company  
MATERIAL SAFETY DATA SHEET

Cardiolite

Page 2 of 6

CARDIOLITE

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

Adverse reactions from clinical administration of CARDIOLITE following reconstitution with Sodium Pertechnetate Tc99m 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 Tc99m is excreted in human milk during lactation. It is not known whether Technetium Tc99m Sestamibi is excreted in human milk.

Carcinogenicity Information

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.

FIRST AID MEASURES

First Aid

INHALATION

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

SKIN CONTACT

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

EYE CONTACT

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. 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

CARDIOLITE, Kit for the Preparation of Technetium Tc99m 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 the patient is conscious, induction of emesis may be indicated. Gastric lavage may be indicated if the patient is unconscious. An 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).

Bristol-Myers Squibb Company  
MATERIAL SAFETY DATA SHEET

Cardiolite

Page 3 of 6

FIRE FIGHTING MEASURES

Flammable Properties

Not expected to be a fire or explosion hazard.

Extinguishing Media

Water Spray, Foam, Dry Chemical, CO<sub>2</sub>.

Fire Fighting Instructions

Keep personnel removed and upwind of fire. Wear self contained breathing apparatus. Wear full protective equipment.

ACCIDENTAL RELEASE MEASURES

Safeguards (Personnel)

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean-up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean-up.

Spill Clean Up

Use HEPA filtered vacuum or wet mop. Do not generate dust.

Accidental Release Measures

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

HANDLING AND STORAGE

Handling (Personnel)

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

Handling (Physical Aspects)

Do not generate dust.

Storage

Do not store or consume food, drink or tobacco in areas where they may become contaminated with this material. Store between 15-25 C (59-77 F).

EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls

Handle in a laboratory fume hood, or other suitably ventilated work area.

Personal Protective Equipment

Wear safety glasses with side shields. Wear full face protection when judged that the possibility exists for eye and face contact.

Wear an appropriate NIOSH approved air purifying respirator or positive pressure air-supplied respirator in situations where a respirator is judged appropriate to prevent inhalation.

Wear impervious clothing such as gloves, lab coat, shoe covers, apron, or jumpsuit, as appropriate. Consult the site safety professional for additional guidance, as needed.

Bristol-Myers Squibb Company  
MATERIAL SAFETY DATA SHEET

Cardiolite

Page 4 of 6

Exposure Guidelines

Exposure Limits

CARDIOLITE

PEL (OSHA) : None Established

TLV (ACGIH) : None Established

PHYSICAL AND CHEMICAL PROPERTIES

Physical Data

pH : 5.0-6.0 after reconstitution

Odor : Slight garlic-like.

Form : Powder.

Color : White.

The solubility of the lyophilized material in water is 25 mg/mL.

CARDIOLITE, Kit for the Preparation of Technetium Tc99m Sestamibi for Injection, is supplied as a 5 mL vial in kits of two, five, and thirty vials, sterile and nonpyrogenic. The contents of the vials are lyophilized and stored under nitrogen.

STABILITY AND REACTIVITY

Chemical Stability

Stable at normal temperatures and storage conditions.

Incompatibility with Other Materials

Mannitol is incompatible with strong oxidizers, including halogen, isocyanates and metal alkalies.

Decomposition

Decomposition will not occur if handled and stored properly.

Polymerization

Polymerization will not occur.

TOXICOLOGICAL INFORMATION

Animal Data

Information on the adverse effects of this material in animal studies by the inhalation, dermal, ocular, or oral route(s) of exposure is not available.

Data on the active component Tetrakis (2-methoxy isobutyl isonitrile) Copper (I) tetrafluoroborate (  $\text{Cu}(\text{MIBI})_4\text{BF}_4$  ) are presented. Data are also presented for mannitol, sodium citrate dihydrate and L-cysteine hydrochloride monohydrate.

Tetrakis (2-methoxy isobutyl isonitrile) Copper (I) tetrafluoroborate

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)

Bristol-Myers Squibb Company  
MATERIAL SAFETY DATA SHEET

Cardiolite

Page 5 of 6

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

**Mutagenicity.**

Tetrakis (2-methoxy isobutyl isonitrile) Copper (I) tetrafluoroborate was not genotoxic in an "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.

**Mannitol**

**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 and Developmental Data**

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.

**Sodium Citrate Dihydrate**

**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

**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.

Bristol-Myers Squibb Company  
MATERIAL SAFETY DATA SHEET

Cardiolite

Page 6 of 6

LD50 is the dose at which lethality occurred in 50% of the animals tested following oral exposure or exposure by injection.

LDLo is the lowest dose at which lethality was noted following exposure by injection.

DISPOSAL CONSIDERATIONS

Waste Disposal

Treatment, storage, transportation, and disposal must be in accordance with applicable Federal, State/Provincial, and Local regulations.

If reconstituted with Technetium Tc-99m, notify your site Radiation Safety Officer and follow spill control and waste management procedures for radioactive materials.

TRANSPORTATION INFORMATION

Shipping Information

The known properties of this material do not constitute a hazard as defined by the U.S. Department of Transportation.

OTHER INFORMATION

NFPA, NPCA-HMIS

NFPA Rating  
Health : 2  
Flammability : 0  
Reactivity : 0

NPCA-HMIS Rating  
Health : 2  
Flammability : 0  
Reactivity : 0

References

Information from research conducted or contracted by Bristol-Myers Squibb.

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.

DMP03729

D0034

For MSDS information contact 732-227-7380.