

CHOLETEC KIT MATERIAL SAFETY DATA SHEET

The author of this Material Safety Data Sheet (MSDS) is Bracco Diagnostics Inc. This MSDS is generated and/or distributed by the Bristol-Myers Squibb Company on behalf of Bracco Diagnostics Inc. Please carefully review all of the information disclosed in this MSDS prior to handling or using the product referenced below.

SECTION 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Bracco Diagnostics Inc.
P.O. Box 5225
Princeton, NJ 08543

Product Identification: CHOLETEC Kit for the Preparation of Technetium Tc 99m Mebrofenin (vials containing lyophilized powder)

1. Chemical Name: For active, mebrofenin. (2,2'-[[2-[(3-Bromo-2,4,6-trimethylphenyl)-amino]-2-oxoethyl]imino]bisacetic acid).
2. Synonyms: For active, mebrofenin: stannous trimethylbromo HIDA.
3. How Supplied: Kits of 10 sterile multidose reaction vials containing lyophilized powder.
4. Product Use: Preparation of Technetium Tc 99m Mebrofenin, an intravenous injection hepatobiliary imaging agent.
5. Chemical Family: Iminodiacetic acid (HIDA) derivative.
6. Molecular Formula: C₁₅H₁₉BrN₂O₅.
7. CAS NUMBER: Mebrofenin (78266-06-5).

EMERGENCY CONTACTS: (Health) 1-800-257-5181.
(U.S. Transportation) Chemtrec 1-800-424-9300.
(International Transportation) Chemtrec
1-703-527-3887.

EMERGENCY OVERVIEW: Vials containing powder. See Health Effects and Toxicology sections for additional information.

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

COMPONENTS (>1%)	HAZARDOUS (Y/N)	CONCENTRATION (w/w%)	CAS NUMBER	EXPOSURE GUIDELINE
Mebrofenin	N	78	78266-06-5	None
Sodium Hydroxide	Y	11	1310-73-2	2 mg/m ³ (TLV-Ceiling)
Methylparaben	N	8	99-76-3	None
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COMPONENTS (>1%)	HAZARDOUS (Y/N)	CONCENTRATION (w/w%)	CAS NUMBER	EXPOSURE GUIDELINE
Stannous Fluoride	Y	1	7783-47-3	2 mg/m3 Inorganic tin cmpds. (TLV-TWA)
Hydrogen chloride	Y	1	7647-01-0	7 mg/m3 (TLV and PEL-C)
Propylparaben	N	1	94-13-3	None

Components present at <1% or used for pH adjustment: not applicable.

SECTION 3: HEALTH HAZARDS IDENTIFICATION

Effects of Overexposure

Routes of Entry:

1. Inhalation: Under normal conditions, this material is handled in closed vials and exposure by inhalation is not expected to occur.
2. Skin Contact: Exposure may occur via skin contact if gloves and protective clothing are not worn. The extent of systemic absorption of the material after skin contact is not known.
3. Ingestion: Ingestion of large quantities of this material in an occupational setting would not be expected to occur. Ingestion of trace amounts of the material might occur if the material contacts hands and hands are not washed prior to eating, drinking or smoking. The extent of systemic absorption after ingestion is not known.

Acute

1. Ingestion: Inadvertent ingestion of trace amounts of this material would not be expected to result in symptoms.
2. Inhalation: Formulation contains some materials that are irritants. Inhaling small amounts of dust may result in irritation.
3. Skin Contact:
 - a. Toxic: Contact with small quantities of material for short periods is not expected to result in pharmacologic or toxic effects.
 - b. Irritation: Material contains components that are irritants. It may have potential to cause mild irritation, however, moderate or severe irritation is not expected.
 - c. Sensitization: This material may act as a sensitizer (allergen) for those persons who are allergic to the formulation or components in the formulation.
4. Eye Contact: May cause irritation.

Chronic

Repeated and prolonged exposure to skin may cause skin irritation.

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Exposure Guideline Summary: An exposure guideline has not been established for this material.

Carcinogen Lists IARC: No. NTP: No. OSHA: No.

Target Organs: None known.

Medical Condition Aggravated by Exposure: Skin disorders may be aggravated by irritant materials.

SECTION 4: FIRST AID MEASURES

1. Ingestion: Get medical attention immediately. Vomiting may be induced if a person is conscious and if ingestion has occurred within the past three hours. Never induce vomiting in a person who is unconscious or experiencing convulsions.
 2. Inhalation: Remove exposed person to fresh air. If person is not breathing, give artificial respiration. If breathing is difficult administer oxygen. Get medical attention immediately.
 3. Skin Contact: Remove contaminated clothing. Wash skin with plenty of water for 5 minutes. Seek medical attention if irritation (redness, itching or swelling) develops or persists.
 4. Eye Contact: Hold eyelids apart and flush with plenty of water for 5 minutes. Get medical attention if signs of irritation develop.
 5. Note to physicians: None.
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SECTION 5: FIRE FIGHTING MEASURES

1. Flash Point: Not available.
 2. Auto-ignition Temperature: Not available.
 3. Flammability Limits:
 - a. LEL: Not applicable.
 - b. UEL: Not applicable.
 4. Combustibility of Dusts: Not available.
 5. Extinguishing Media: In case of fire, flood with water.
Fire-fighting Instructions: Firefighters should wear self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves. Evacuate personnel to an upwind direction, remove unneeded material and cool container(s) with water from a maximum distance.
 6. Hazardous Combustion Products: Carbon monoxide, carbon dioxide, hydrogen bromide, hydrogen chloride, hydrogen cyanide, hydrogen fluoride, nitrogen oxides.
 7. Unusual Hazards: None.
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SECTION 6: ACCIDENTAL RELEASE MEASURES

Spill/Clean-up: Lab coat, impermeable gloves (latex, latex/nitrile or nitrile) and eye protection should be worn as a minimum precaution. Sweep material onto paper and place into a fiber drum for reclamation or disposal. The spill area should be ventilated and decontaminated after material has been picked up.

SECTION 7: HANDLING AND STORAGE

Handling Precautions: Avoid skin and eye contact.

1. Container Requirements: Kits of 10 reaction vials.
 2. Storage Conditions: Store at 20-25 degrees C.
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SECTION 8: EXPOSURE CONTROLS & PERSONAL PROTECTION

1. Ventilation Requirements: None beyond good room ventilation.
 2. Respiratory Protection: Not anticipated for normal clinical environment. Non-routine exposure conditions may require NIOSH approved respiratory protection appropriate for exposure potential. Self-contained breathing apparatus should be available for emergency use.
 3. Eye Protection: Wear safety glasses (ANSI Z87.1).
 4. Protective Gloves: Wear impervious gloves (latex, latex/nitrile, or nitrile) if the potential exists for dermal contact.
 5. Special Clothing: None.
 6. Hygiene: Wash hands after handling product and before eating, smoking, using lavatory and at the end of the day.
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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

1. Appearance/Physical State/Color: Powder.
 2. Boiling Point: Not applicable.
 3. Evaporation Rate: Not applicable.
 4. Flash Point: Not available.
 5. Freezing point/Melting Point: Not available/198-200 degrees C.
 6. Octanol/Water Partition Coefficient: Not available.
 7. Odor (threshold): Not available.
 8. pH: 4.2 to 5.7 (reconstituted solution)
 9. Solubility in Water: Soluble.
 10. Specific Gravity: Not available for lyophile, for reconstituted solution, 1.018.
 11. Vapor Density: Not available.
 12. Vapor Pressure: Minimal, material exists as a solid.
 13. Viscosity (cP): Not applicable.
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SECTION 10: STABILITY AND REACTIVITY

1. Stability: Filled containers are stable under normal conditions. Shelf-life indicated on individual containers.
 2. Incompatibilities: None known.
 3. Conditions of Reactivity: Reactive with metals as chelating or complexing agent.
 4. Hazardous Decomposition Products: Carbon monoxide, carbon dioxide, hydrogen bromide, hydrogen chloride, hydrogen cyanide, hydrogen fluoride, nitrogen oxides.
 5. Hazardous Polymerization: None.
 6. Explosion data relative to mechanical impact: No information.
 7. Explosion data relative to static discharge: No information.
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SECTION 11: TOXICOLOGICAL INFORMATION - for active ingredient, mebrofenin.

1. RTECS # (U.S.): MB9121850
 2. Acute toxicity data:
 - Acute iv LD50(mouse)= 213.8 mg/kg;
 - Acute iv LD50(rat)= 226.4 mg/kg.
 3. Chronic:
 - a. Carcinogenicity: No information.
 - b. Mutagenicity: No information.
 - c. Teratogenicity: No information.
 - d. Reproductive Effects: No information.
 - e. Toxicological Synergistic Products: No information.
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SECTION 12: ECOLOGICAL INFORMATION

1. Ecotoxicological Information: Not available.
 2. Chemical Fate Information: Not available.
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SECTION 13: DISPOSAL CONSIDERATIONS

Dispose in accordance with national, state, local or applicable country regulations.

SECTION 14: TRANSPORT INFORMATION

1. Domestic
 - a. Proper Shipping Name: Not classified.
 - b. Hazard Class, UN Number, Packing Group: Not classified.
 - c. Label Requirements: Not applicable.
 - d. Placard Requirements: Not applicable.

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2. International

- a. Proper Shipping Name: Not classified.
 - b. Hazard Class, UN Number, Packing Group: Not classified.
 - c. Label Requirements: Not applicable.
 - d. Placard Requirements: Not applicable.
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SECTION 15: REGULATORY/STATUTORY INFORMATION (limited to health, safety, environmental)

NOTE: Not meant to be all-inclusive.

- 1. U.S. Federal: None noted.
 - 2. International: None noted.
 - 3. EC Labeling: Not applicable.
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SECTION 16: OTHER INFORMATION

December 22, 2000: New MSDS for Choletec Kit was developed by Bracco Diagnostics, Inc.

March 6, 1992: Bristol-Myers Squibb MSDS for CHOLETEC Kit.

When sterile, pyrogen-free, sodium pertechnetate Tc 99m injection (a radioactive material) is added to the CHOLETEC Kit vial, the diagnostic agent Technetium Tc 99m mebrofenin is formed. The resulting material is radioactive.

When transporting an employee for medical assistance, after the employee has had direct contact with a radioactive material, care should be taken to avoid contamination of transport vehicle and medical facility. Skin decontamination and monitoring should be conducted as appropriate.

If ingestion of the prepared kit, containing radioactive Technetium Tc 99m, inadvertently occurs, the individual may be treated by water hydration or diuresis to facilitate elimination of the radioactive material.

Radioactive materials may pose significant health risks if not properly handled. Personnel who handle radioactive materials should be trained in their use and should follow appropriate precautions for work with these materials.

Technetium Tc 99m decays by isomeric transition with a physical half-life of 6.02 hours. The specific gamma ray constant for Tc 99m is 0.78 R/hour-millicurie at 1 cm. The first half value layer is 0.2 mm of lead (Pb).

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Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides) and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Dispose of radioactive material in accordance with all local, state, federal and NRC regulations or with the regulations of the country in which the material is used.

Diagnostic agents are intended for use under direction of a physician and under the conditions of use described on the label and the product's package insert. As a general precaution, personnel who handle these products should avoid contact (ingestion, inhalation, skin and eye contact) with them.

This material safety data sheet is intended for use by personnel who handle this material as part of their job responsibilities and it does not address the diagnostic use of this material. Information concerning the use of this diagnostic agent should be obtained from the product package insert and other appropriate references.

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