1 Identification

Product identifier

Sheet Code: 278

Trade name: Choletec Kit for the Preparation of Technetium Tc 99m Mebrofenin

Chemical Name:
For active (Mebrofenin): 2,2’-[2-{(3-Bromo-2,4,6-trimethylphenyl)-amino]-2-oxoethyl}imino]bisacetic Acid
Synonyms: For Active (Mebrofenin): Stannous Trimethylbromo HIDA (Iminodiacetic acid).

How Supplied: Kits of 10 sterile multidose reaction vials containing lyophilized powder

Relevant identified uses of the substance or mixture and uses advised against
We recommend that you use this product in a manner consistent with the listed use. If your intended use is not consistent with the stated use, please contact your sales or technical service representative.

Application of the substance / the mixture:
Preparation of Technetium Tc 99m Mebrofenin, an intravenous injection hepatobiliary imaging agent.

Chemical Family: Iminodiacetic acid (HIDA) derivative.

Molecular Formula: C15H19BrN2O5

CAS Number: 78266-06-5

Details of the supplier of the safety data sheet

Manufacturer/Supplier:
Bracco Diagnostics Inc.
P.O. Box 5225
Princeton, NJ 08543

Emergency telephone number:

Emergency Overview:
Vials containing powder.
See Health Effects and Toxicology sections for additional

2 Hazard(s) identification

Classification of the substance or mixture

GHS05 Corrosion

Skin Corr. 1A  H314  Causes severe skin burns and eye damage.
Eye Dam. 1  H318  Causes serious eye damage.

Label elements

GHS label elements
The product is classified and labeled according to the Globally Harmonized System (GHS).

Hazard pictograms GHS05

Signal word Danger
Trade name: Choletec Kit for the Preparation of Technetium Tc 99m Mebrofenin

Hazard-determining components of labeling:
Sodium Hydroxide

Hazard statements
Causes severe skin burns and eye damage.

Precautionary statements:
Wash thoroughly after handling.
Wear eye protection / face protection.
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Immediately call a poison center/doctor.
Specific treatment (see on this label).
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

Effects of Overexposure - Routes of Entry:
Inhalation:
Under normal conditions, this material is handled in closed vials and exposure by inhalation is not expected to occur.

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.

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.

Additional Information:
WHMIS-symbols:
D2B - Toxic material causing other toxic effects
E - Corrosive material

Information pertaining to particular dangers for man and environment:
Negative Effects on the Health: See also Sections 11
Negative Effects on the Environment: See also Section 12

NFPA ratings (scale 0 - 4)

Health = 3
Fire = 0
Reactivity = 0

HMIS-ratings (scale 0 - 4)

Health = 4
Fire = 0
Reactivity = 0

Results of PBT and vPvB assessment
PBT: Not applicable.
**3 Composition/information on ingredients**

**Chemical characterization: Substances**
Impurities and stabilising additives: None

**Chemical characterization: Mixtures**

**Description:** Mixture consisting of the following components.

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS / EINECS / Index number</th>
<th>Hazardous Components</th>
<th>Risk Phrases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Hydroxide</td>
<td>1310-73-2 / 215-185-5 / 011-002-00-6</td>
<td>Sodium Hydroxide</td>
<td>Skin Corr. 1A, H314</td>
</tr>
<tr>
<td>tin difluoride</td>
<td>7783-47-3 / 231-999-3 / 017-002-01-X</td>
<td>tin difluoride</td>
<td>Acute Tox. 3, H301</td>
</tr>
<tr>
<td>hydrochloric acid</td>
<td>231-595-7 / 017-002-01-X / RTECS: MW 9620000</td>
<td>hydrochloric acid</td>
<td>Skin Corr. 1B, H314; STOT SE 3, H335</td>
</tr>
</tbody>
</table>

**Additional information:** For the wording of the listed risk phrases refer to section 16.

**4 First-aid measures**

**Description of first aid measures**

**General information:** No special measures required.

**After Inhalation:**
Supply fresh air. If required, provide artificial respiration.

**After 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.

**After Eye Contact:**
Wash with running water for several minutes holding the eyelids open. If any symptoms of irritation develop and / or persist, consult your doctor.

**After Swallowing:**
Get medical attention immediately. Vomiting may be induced only 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.

**Most important symptoms and effects, both acute and delayed** See also Section 2 and 11.

**Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

**Means of Specific and Immediate Treatment to Keep at the Workplace:** No special measures required.

**Note to physicians:** None.

**5 Fire-fighting measures**

**Extinguishing media**

**Suitable extinguishing agents:** In case of fire, flood with Water
**Trade name:** Choletec Kit for the Preparation of Technetium Tc 99m Mebrofenin

---

**For safety reasons unsuitable extinguishing agents:** Unknown.

**Special hazards arising from the substance or mixture** See also Section 10.

**Additional Information:** Not Available

**Advice for Firefighters**
Evacuate personnel to an upwind direction, remove unneeded material and cool container(s) with water from a maximum distance.
Move container from fire area if you can do it without risk.

**Protective Equipment:**
Firefighters should wear adequate personal protective equipment with protection of respiratory tract (self-contained breathing apparatus) (SCBA).
Wear flame and chemicals resistant clothing, boots and gloves (see Section 8).

---

### 6 Accidental release measures

**Personal precautions, protective equipment and emergency procedures**
Wear protective equipment appropriate to the circumstances (see Section 8)
Avoid inhalation of dust / fog.

**Environmental precautions:** Do not allow product to reach sewage system or any water course.

**Methods and material for containment and cleaning up:**
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.

**Reference to other sections**
See Section 7 for information on Safe Handling.
See Section 8 for information on Personal Protection Equipment.
See Section 13 for Disposal Information.
See Section 12 for Ecological Information.

---

### 7 Handling and storage

**Precautions for Safe Handling** Avoid skin and eye contact.

**Conditions for Safe Storage, including any Incompatibilities**

**Requirements to be met by Storerooms and Receptacles:**
Store in a cool, dry place in tightly closed receptacles.

**Container Requirements:** Kits of 10 reaction vials.

**Storage Conditions:** Store at 20-25 degrees C.

**Information about Storage in one Common Storage Facility:** Not required.

**Further information about storage conditions:** None.

**Specific end use(s)** No further relevant information available.

---

### 8 Exposure controls/personal protection

**Additional information about design of technical systems:** No further data; see item 7.

**Control parameters**

**Components with limit values that require monitoring at the workplace:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1310-73-2 Sodium Hydroxide</td>
<td>2 mg/m³ absolute limit value for 2009</td>
</tr>
<tr>
<td>TLV-ACGIH (USA)</td>
<td>Long-term value: 2 mg/m³</td>
</tr>
</tbody>
</table>

---
Trade name: Choletec Kit for the Preparation of Technetium Tc 99m Mefrofenin

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Chemical Name</th>
<th>PEL (USA)</th>
<th>REL (USA)</th>
<th>TLV (USA)</th>
<th>IOELV (EU)</th>
<th>EL (Canada)</th>
<th>EV (Canada)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7783-47-3</td>
<td>BRACCO tin difluoride</td>
<td>Long-term value: 2 mg/m³ as Sn</td>
<td>Long-term value: 2 mg/m³ as Sn</td>
<td>Long-term value: 2 mg/m³ as Sn</td>
<td>Long-term value: 2 mg/m³ as Sn</td>
<td>Long-term value: 2 mg/m³ as Sn</td>
<td>Long-term value: 2 mg/m³ as Sn</td>
</tr>
</tbody>
</table>

Additional information: The lists that were valid during the creation were used as a basis.

Exposure controls

Appropriate Technical Controls: Provide adequate aspiration / ventilation in the workplace.

Additional information about Design of Technical Facilities: No further data (see Section 7).

Personal protective equipment

General Protective and Hygienic Measures:
The usual precautionary measures for handling chemicals should be followed.
Wash hands before breaks and at the end of work.
Wear protective equipment (PPE) appropriate to the circumstances.

Do not eat, drink, smoke while working.

Breathing Equipment:
Not anticipated for normal clinical environment.
In non-routine exposure conditions, where risk assessment shows air-purifying respirators are appropriate, use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Self-contained breathing apparatus should be available for emergency use.

Protection of Hands:

Wear impervious gloves if the potential exists for dermal contact.

Material of Gloves:
Latex, Latex / Nitrile or Nitrile Gloves.
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
The glove material has to be impermeable and resistant to the product/ the substance/ the mixture.

Penetration Time of Glove Material:
The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.
**Trade name:** Choletec Kit for the Preparation of Technetium Tc 99m Mebrofenin

**Eye Protection:**
Tightly sealed goggles

**Body Protection:**
In the case of high concentrations of dust, we recommend using lightweight disposable protective clothing

**Limitation and Supervision of Exposure into the Environment:** See also Section 7.

**Additional Information about Design of Technical Systems:** No further data; see Section 7.

---

**9 Physical and chemical properties**

**Information on basic physical and chemical properties**

**General Information**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance:</strong></td>
<td>Powder</td>
</tr>
<tr>
<td><strong>Form:</strong></td>
<td>Powder</td>
</tr>
<tr>
<td><strong>Odour threshold:</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>pH-value:</strong></td>
<td>4.2 - 5.7 (Reconstituted Solution)</td>
</tr>
<tr>
<td><strong>Flash point:</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td>**Flammability (solid, gaseous):</td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Ignition temperature:</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Decomposition temperature:</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Auto igniting:</strong></td>
<td>Product is not selfigniting.</td>
</tr>
<tr>
<td><strong>Danger of explosion:</strong></td>
<td>Product does not present an explosion hazard.</td>
</tr>
<tr>
<td><strong>Density:</strong></td>
<td>1.018 g / cm³ (Reconstituted Solution)</td>
</tr>
<tr>
<td><strong>Relative density</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Vapour density</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Solubility in / Miscibility with Water:</strong></td>
<td>Soluble.</td>
</tr>
<tr>
<td><strong>Partition coefficient (n-octanol/water):</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Viscosity:</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Dynamic:</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Kinematic:</strong></td>
<td>Not applicable.</td>
</tr>
</tbody>
</table>

**Other information**
No further relevant information available.

---

**10 Stability and reactivity**

**Reactivity:** There are not particular dangerous reactions with other substances in normal conditions of use.

**Chemical stability:**
Stable under normal conditions.
Shelf-life indicated on individual containers.

**Possibility of hazardous reactions:** Reactive with metals as chelating or complexing agent.
**Conditions to avoid:**
Simultaneous presence of air and dust ignition sources: the dusts suspended in air and in the presence of primers of sufficient energy are a potential danger of explosion.
Lower Explosive Limit and Ignition Energy are not available

**Incompatible materials:** No further relevant information available.

**Hazardous decomposition products:** No further relevant information available (See Section 5)

11 Toxicological information

**Information on toxicological effects**

**Acute toxicity:**

**Toxicological Information for Active Ingredients:**

<table>
<thead>
<tr>
<th>LD/LC50 values that are relevant for classification:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>78266-06-5 Mebrofenin</strong></td>
</tr>
<tr>
<td>LD50 iv 213.8 g (Iodine) /kg (Mouse)</td>
</tr>
<tr>
<td>226.4 mg/kg (Rat)</td>
</tr>
<tr>
<td><strong>1310-73-2 Sodium Hydroxide</strong></td>
</tr>
<tr>
<td>Oral LD50 2000 mg/kg (Rat)</td>
</tr>
<tr>
<td><strong>99-76-3 Methylparaben</strong></td>
</tr>
<tr>
<td>Oral LD50 6000 mg/kg (Rabbit)</td>
</tr>
<tr>
<td><strong>hydrochloric acid</strong></td>
</tr>
<tr>
<td>Oral LD50 900 mg/kg (Rabbit)</td>
</tr>
<tr>
<td><strong>94-13-3 Propylparaben</strong></td>
</tr>
<tr>
<td>Oral LD50 6332 mg/kg (Mouse)</td>
</tr>
</tbody>
</table>

**Primary irritant effect:**

**By Inhalation:**
Formulation contains some materials that are irritants. Inhaling small amounts of dust/powder may result in irritation.

**By Ingestion:**
Inadvertent ingestion of trace amounts of this material would not be expected to result in symptoms.

on the skin:
Material contains low concentration of components that are mild irritants or possible irritants. It may have potential to cause mild irritation, however, moderate or severe irritation is not expected.

on the eyes: Not Available.

on the skin: No irritant effect.

on the eye: No irritating effect.

**Sensitization:**
This material may act as a sensitizer (allergen) for those persons who are allergic to the formulation or components in the formulation.

**Sensitization:** No sensitizing effects known.

**Single Exposure (STOT - SE):** No further relevant information available

**Repeated Exposure (STOT - RE):** No further relevant information available

**Other information (about experimental toxicology):** No further relevant information available
Trade name: Cholec Kit for the Preparation of Technetium Tc 99m Mebrofenin

Carcinogenic categories

<table>
<thead>
<tr>
<th>Agency</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>IARC (International Agency for Research on Cancer)</td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td>NTP (National Toxicology Program)</td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td>OSHA-Ca (Occupational Safety &amp; Health Administration)</td>
<td>None of the ingredients is listed.</td>
</tr>
</tbody>
</table>

Additional toxicological information:
Contact with small quantities of material for short periods is not expected to result in pharmacologic or toxic effects.
Skin disorders may be aggravated by irritant materials.

12 Ecological information

Toxicity

Aquatic toxicity:
1310-73-2 Sodium Hydroxide
LC50 180 mg/l (Fish)

Persistence and degradability
No further relevant information available.

Bioaccumulative potential
No further relevant information available.

Mobility in soil:
No further relevant information available.

General notes:
Water hazard class 1 (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
Avoid transfer into the environment.

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

Other adverse effects
No further relevant information available.

Additional Information: Use according to good working pratice.

13 Disposal considerations

Waste treatment methods:
Recommendation:
Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Reutilise if possible or contact a waste processors for recycling or safe disposal.

Uncleaned packagings:
Recommendation: Dispose in accordance with national, state, local or applicable country regulations.
Recommended cleansing agent: Water, if necessary with cleansing agents.

14 Transport information

UN-Number
DOT, ADR, IMDG, IATA
UN1759
### Trade name: Choletec Kit for the Preparation of Technetium Tc 99m Mebrofenin

<table>
<thead>
<tr>
<th><strong>UN proper shipping name</strong></th>
<th>CORROSIVE SOLID, N.O.S. (Mebrofenin, SODIUM HYDROXIDE)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ADR</strong></td>
<td>1759 CORROSIVE SOLID, N.O.S. (Mebrofenin, SODIUM HYDROXIDE)</td>
</tr>
</tbody>
</table>

**Transport hazard class(es)**

- **ADR, IMDG, IATA**

<table>
<thead>
<tr>
<th><strong>Class</strong></th>
<th>8 Corrosive substances</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Label</strong></td>
<td>8</td>
</tr>
</tbody>
</table>

**Packing group**

- **DOT, ADR, IMDG, IATA**

| **Packing group** | 1 |

**Environmental hazards:**

- **Marine pollutant:** No
- **Special precautions for user:** Warning: Corrosive substances
- **Danger code (Kemler):** 88
- **EMS Number:** F-A-S-B
- **Segregation groups:** Alkalis

**Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

- Not applicable.

**Transport/Additional information:**

- **ADR**
  - **Excepted quantities (EQ):** E0
  - **Transport category:** 1
- **UN "Model Regulation":** UN1759, CORROSIVE SOLID, N.O.S. (Mebrofenin, SODIUM HYDROXIDE), 8, I

### 15 Regulatory information

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

- **Sara**
  - **Section 355 (extremely hazardous substances):** None of the ingredients is listed.
  - **Section 313 (Specific toxic chemical listings):** None of the ingredients is listed.

- **TSCA (Toxic Substances Control Act):**
  1310-73-2 Sodium Hydroxide
  99-76-3 Methylparaben
  7783-47-3 tin difluoride
  94-13-3 Propylparaben
Trade name: Choletec Kit for the Preparation of Technetium Tc 99m Mebrofenin

Proposition 65

**Chemicals known to cause cancer:**
None of the ingredients is listed.

**Chemicals known to cause reproductive toxicity for females:**
None of the ingredients is listed.

**Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

**Chemicals known to cause developmental toxicity:**
None of the ingredients is listed.

Carcinogenic categories

**EPA (Environmental Protection Agency)**
None of the ingredients is listed.

**TLV (Threshold Limit Value established by ACGIH)**
None of the ingredients is listed.

**NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

**Hazard pictograms** GHS05

**Signal word** Danger

**Hazard-determining components of labeling:**
Sodium Hydroxide

**Hazard statements**
Causes severe skin burns and eye damage.

**Precautionary statements**
Wash thoroughly after handling.
Wear eye protection / face protection.
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Immediately call a poison center/doctor.
Specific treatment (see on this label).
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

### 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

**Description and Property:**
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.

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).

**Significant Dangers:**
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 other personnel, 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.

**Relevant phrases**

H301 Toxic if swallowed.
H314 Causes severe skin burns and eye damage.
H335 May cause respiratory irritation.

**Training Hints:**

All persons handling this product should be informed on the existence of the hazard, on any possible risk they might be subjected to and about all required protective measures to prevent such a damage or to reduce the exposition.

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.

**WARNINGS:**

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

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.

Technetium Tc 99m Mebrofenin is a RADIOACTIVE MATERIAL.