

Safety Data Sheet

According to OSHA HazCom Standard [2012]

Printing date 08/28/2019

Version 2

Reviewed on 08/28/2019

1 Identification

Product identifier

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

Application of the substance / the mixture:

Preparation of Technetium Tc 99m Mebrofenin, an intravenous injection hepatobiliary imaging agent. 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.

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

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 CONTACT:

Health: 1-800-257-5181
U.S. Transport - Chemtrec: 1-800-424-9300
International Transport - Chemtrec: 1-703-527-3887
Nuclear Regulatory Commission: 1-800-368-5642

2 Hazard(s) identification

Classification of the substance or mixture

The product is not classified, according to the Globally Harmonized System (GHS).

Label elements

GHS label elements Not applicable.

Hazard pictograms Not applicable.

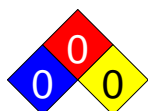
Signal word Not applicable.

Hazard statements Not applicable.

Additional Information:

Classification system:

NFPA ratings (scale 0 - 4)



Health = 0
Fire = 0
Reactivity = 0

HMIS-ratings (scale 0 - 4)



Health = *0
Fire = 0
Reactivity = 0

Other hazards No further relevant information available.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

3 Composition/information on ingredients

Chemical characterization: Mixtures

Description: Mixture: consisting of the following components.

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Hazardous Components:		
	hydrochloric acid Skin Corr. 1B, H314; Eye Dam. 1, H318; Acute Tox. 4, H302; STOT SE 3, H335	≥0.5-<2%
1310-73-2	Sodium Hydroxide Skin Corr. 1A, H314; Acute Tox. 4, H302	≥0.5-<2%
7783-47-3	tin difluoride Acute Tox. 3, H301	<2.5%
Non-Hazardous Components:		
78266-06-5	Mebrofenin	50-100%

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.

If breathed in, move person into fresh air. When symptoms persist or in all cases of doubt seek medical advice

After skin contact:

Remove/ Take off immediately all contaminated clothing.

Wash off immediately with soap and plenty of water for at least 15 minutes.

Seek medical attention if irritation (redness, itching or swelling) develops or persists

After eye contact:

Rinse immediately with plenty of water, also under the eyelids for at least 15 minutes.

If any symptoms of irritation develop and / or persist, consult your doctor.

After swallowing:

Call for a doctor 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

No further relevant information available.

Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire-fighting measures

Extinguishing media

Suitable extinguishing agents: Water spray

Special hazards arising from the substance or mixture No further relevant information 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:

Wear NIOSH/MSHA approved self-contained breathing apparatus and protective clothing.

Wear fully protective suit.

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

Avoid inhaling dust and fumes.

Environmental precautions: Do not allow to enter sewers/ surface or ground water.

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Trade name: Choletec Kit for the Preparation of Technetium Tc 99m Mebrofenin**Methods and material for containment and cleaning up:**

Retrieve product by mechanical means.

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

No dangerous substances are released.

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

Precautions for safe handling Avoid contact with the eyes and skin.**Information about protection against explosions and fires:** No special measures required.**Conditions for safe storage, including any incompatibilities****Requirements to be met by storerooms and receptacles:**

Store in a cool, dry location in well sealed 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

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

The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

At this time, the other constituents have no known exposure limits.

1310-73-2 Sodium Hydroxide

TLV-ACGIH	Long-term value: 2 mg/m ³ absolute limit value for 2009
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Additional information: The lists that were valid during the creation were used as basis.**Exposure controls****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.

Ensure good ventilation/exhaustion at the workplace.



Do not eat, drink and 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.

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

Protective gloves

The glove material must be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

Natural rubber, NR

Nitrile rubber, NBR

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:

Tightly sealed goggles

Body protection:

Protective work clothing

In the case of high concentrations of dust, we recommend using lightweight disposable protective clothing

9 Physical and chemical properties

Information on basic physical and chemical properties**General Information****Appearance:****Form:** Powder**Odor threshold:** Not determined.**pH-value:** 4.2 - 5.7 (Reconstituted Solution)**Melting point/Melting range:** Not determined.**Boiling point/Boiling range:** 198 - 200 °C**Flash point:** Not applicable.**Flammability (solid, gaseous):** Not determined.**Decomposition temperature:** Not determined.**Auto igniting:** Product is not selfigniting.**Danger of explosion:** Product does not present an explosion hazard.**Explosion limits:****Lower:** Not determined.**Upper:** Not determined.**Vapor pressure:** Not applicable.**Density:** 1.018 g / cm³ (Reconstituted Solution)**Relative density** Not determined.**Vapor density** Not applicable.**Evaporation rate** Not applicable.

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Trade name: Choletec Kit for the Preparation of Technetium Tc 99m Mebrofenin**Solubility in / Miscibility with****Water:** Soluble.**Partition coefficient (n-octanol/water):** Not determined.**Viscosity:****Dynamic:** Not applicable.**Kinematic:** Not applicable.**Other information**

No further relevant information available.

10 Stability and reactivity**Reactivity** No data available.**Chemical stability**

Stable under normal conditions.

Shelf-life indicated on individual containers

Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

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 dangerous decomposition products known.**11 Toxicological information****Information on toxicological effects****Acute toxicity:****LD/LC50 values that are relevant for classification:****78266-06-5 Mebrofenin**

LD50 iv	213.8 g (Iodine) /kg (Mouse)
	226.4 mg/kg (Rat)

1310-73-2 Sodium Hydroxide

Oral	LD50	2000 mg/kg (Rat)
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99-76-3 Methylparaben

Oral	LD50	6000 mg/kg (Rabbit)
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hydrochloric acid

Oral	LD50	900 mg/kg (Rabbit)
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94-13-3 Propylparaben

Oral	LD50	6332 mg/kg (Mouse)
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Primary irritant effect:**on the skin:** No irritant effect.**on the eye:** No irritating effect.**Sensitization:**

No sensitizing effects known.

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

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Trade name: Choletec Kit for the Preparation of Technetium Tc 99m Mebrofenin**Additional toxicological information:**

The product is not subject to classification according to internally approved calculation methods for preparations.

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

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.

Carcinogenic categories**IARC (International Agency for Research on Cancer)**

None of the ingredients are listed.

NTP (National Toxicology Program)

None of the ingredients are listed.

OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients are listed.

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.

Additional ecological information**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.

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: Disposal must be made according to official regulations.

Recommended cleansing agent: Water, if necessary with cleansing agents.

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14 Transport information

UN-Number

DOT, ADR, IMDG, IATA

Not applicable.

UN proper shipping name

DOT, ADR, IMDG, IATA

Not applicable.

Transport hazard class(es)

DOT, ADR, ADN, IMDG, IATA

Class

Not applicable.

Packing group

DOT, ADR, IMDG, IATA

Not applicable.

Environmental hazards:**Marine pollutant:**

No

Special precautions for user

Not applicable.

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

Not applicable.

15 Regulatory information

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

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

Sara**Section 355 (extremely hazardous substances):**

None of the ingredients are listed.

Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

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 are listed.

Chemicals known to cause reproductive toxicity for males:

None of the ingredients are listed.

Chemicals known to cause developmental toxicity:

None of the ingredients are listed.

Carcinogenic categories**EPA (Environmental Protection Agency)**

None of the ingredients are listed.

TLV (Threshold Limit Value established by ACGIH)

None of the ingredients are listed.

NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients are listed.

GHS label elements Not applicable.**Hazard pictograms** Not applicable.**Signal word** Not applicable.**Hazard statements** Not applicable.

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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.

Date of preparation / last revision 08/28/2019 / 1

Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Acute Tox. 3: Acute toxicity – Category 3

Acute Tox. 4: Acute toxicity – Category 4

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3