

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.

Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Bracco Diagnostics Inc.
P.O. Box 5225
Princeton, NJ
08543
Phone number: 1-800-257-5181
Email: HSE@bracco.com (responsible for the SDS)

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

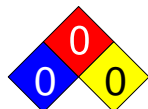
Signal word: Not applicable

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:

Results of PBT and vPvB assessment

PBT: Not applicable

vPvB: Not applicable

3 Composition/information on ingredients

Chemical characterization: Mixtures

Description: Mixtures consisting of the following components.

Hazardous Components			
CAS No.	Name	Classification	Qty.
7647-01-0	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 Fluoride	Acute Tox. 3, H301	< 2.5 %

Non-Hazardous Components		
CAS No.	Name	Qty.
78266-06-5	Mebrofenin	50 – 100 %

Additional information

No further relevant information available.

4 First-aid measures

Description of first aid measures

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 persist.

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

Unsuitable extinguishing agents: None in particular

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

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.

Kits of 10 reaction vials.

Store at 20-25 °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 constituent have no known exposure limit.

1310-73-2	Sodium Hydroxide
TLV-ACGIH	Long-term value: 2 mg/m ³ Absolute limit value for 2009

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.

Protection of hands:



Protective Gloves

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

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
Color:	Not determined
Odor:	Not determined
Odor threshold:	Not determined
pH – Value:	4.2 – 5.7
Melting point/Melting range:	Not determined
Boiling point/Boiling range:	198 – 200 °C
Flash Point:	Not applicable
Flammability (Solid, Gaseous)	Not determined
Ignition temperature:	Product is not self-igniting
Danger of explosion:	Product does not present an explosion hazard
Flammability Limits	
Lower:	Not determined
Upper:	Not determined
Explosion Limits	
Lower:	Not determined
Upper:	Not determined
Oxidizing properties:	Not determined
Vapor pressure:	Not applicable
Density	1.018 g/cm ³
Relativity Density at 20° C (68° F):	Not determined
Vapor Density at 20° C (68° F):	Not determined
Evaporation rate:	Not applicable
Solubility in / Miscibility with	
Water:	Soluble
Partition coefficient (n-octanol/water):	Not determined

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According to OSHA HazCom Standard [2012]

Printing date: **01/01/2023** Reviewed on: **01/01/2023** Version **03**

Viscosity	
Dynamic:	Not applicable
Kinematic:	Not applicable
Water:	Not applicable
VOC Content:	Not applicable
Solid Content:	Not applicable
Other Information:	No further relevant information available

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)

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1310-73-2	Sodium Hydroxide	
Oral	LD50	2000 mg/kg (Rat)
99-76-3	Methylparaben	
Oral	LD50	6000 mg/kg (Rabbit)
7647-01-0	Hydrochloric Acid	
Oral	LD50	900 mg/Kg (Rabbit)
94-13-3	Propylparaben	
Oral	LD50	6332 mg/kg (Mouse)

Primary irritant effect:

on the skin: No irritating 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 components in the formulation.

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

Bio accumulative 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 packaging:

Recommendation:

Disposal must be made according to official regulations.

Recommended cleansing agent:

Water, if necessary with cleansing agents.

14 Transport information

UN Number

DOT, ADR, ADN, IMDG, IATA

Not applicable

UN proper shipping name:

DOT, ADR, ADN, 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 MARPOL 73/78 and the IBC code

Not applicable

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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 are listed

Section 313 (Specific toxic chemical listings):

None of the ingredients are listed

Proposition 65

Chemicals known to cause cancer:

None of the ingredients are 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 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)

Sodium Hydroxide

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

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. 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.

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

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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.

Contact:

Bracco Diagnostics Inc.
P.O. Box 5225
Princeton, NJ 08543
HSE@bracco.com

Date of preparation / last revision: 01/01/2023, revision 03

Changes: General revision.

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)

HMS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Acute Tox. 3: Acute toxicity – Category 3