

# SAFETY DATA SHEET

United States



Version 3.0; January 11, 2019

---

## Section 1. Product and Company Identification

**Product Name:** **MEBROFENIN ®**

**Catalogue Number:** N/A

**Grade:** **Pharmaceutical Reagent**

**Tradenames and Synonyms:** Kit for the Preparation of Technetium Tc 99m Mebrofenin Diagnostic for Intravenous Use  
**For active:** Mebrofenin; stannous trimethylbromo HIDA (Iminodiacetic acid)

**Recommended Use:** Diagnostic Medical Agent. Diagnostic radiopharmaceutical imaging agent after reconstitution with radioactive Technetium Tc 99m.

**Restrictions for Use:** After reconstitution with Technetium Tc 99m, this material must be handled only by trained health care professionals qualified to handle radioactive material.

### Company Identification:

**Pharmalucence Inc.**  
**29 Dunham Road**  
**Billerica, MA 01821**

Phone : + 1-781-275-7120 / 1-800-221-7554

Fax: + 781.275.2634

Hours of operation: (8:30am - 5:00pm)

Web Site: [www.pharmalucence.com](http://www.pharmalucence.com)

---

## Section 2. Hazards identification

**OSHA/HCS status:** While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

**Classification of the substance or mixture:** Does not present hazards within the GHS list of Physical Hazard Classes.

### Health Hazards:

#### For the kit non-reconstituted:

Skin & Eyes Contact: Not established

Inhalation: Not established.

Ingestion: Not established.

#### Label Elements:

Symbol: Not applicable

Signal Word: Not applicable

#### Precautions:

Read the Package Insert prior to use.

Promptly remove any contamination from skin, eyes or clothing. Avoid all unnecessary exposure to the chemical substance.

**Eye contact:** Not expected to be a health hazard.

**Skin contact:** Not expected to be a health hazard.

**Inhalation:** Not expected to be a health hazard.

**Ingestion:** Not expected to be a health hazard.

**Chronic exposure:** Not expected to be a health hazard.

**Aggravation of pre-existing Conditions:** No information found.

# SAFETY DATA SHEET

United States



Version 3.0; January 11, 2019

## Section 3. Composition/information on ingredients

Substance/mixture: Mixture.  
Other means of identification: Not available.

### Composition

Chemical Ingredients Component (quantity per vial):	CAS #	Wt %
Mebrofenin (45 mg)	78266-06-5	88.7 %
Methylparaben, USP (4.5 mg)	99-76-3	8.9 %
Propylparaben, USP (0.5 mg)	94-13-3	1.0 %
Stannous Flouride (0.73 mg)	7783-47-3	1.4 %

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

## Section 4. First aid measures

### Description of necessary first aid measures

**Eye contact** Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

**Inhalation** Remove person to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.

**Skin contact** Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

**Ingestion** Wash out mouth with water. Remove person to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

### Most important symptoms/effects, acute and delayed

#### Potential acute health effects:

**Eye contact** No known significant effects or critical hazards.  
**Inhalation** No known significant effects or critical hazards.  
**Skin contact** No known significant effects or critical hazards.  
**Ingestion** No known significant effects or critical hazards.

### Over-exposure signs/symptoms

**Eye contact** No specific data.  
**Inhalation** No specific data.  
**Skin contact** No specific data.  
**Ingestion** No specific data.

### Indication of immediate medical attention and special treatment needed, if necessary

**Notes to physician** Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.  
**Specific treatments** No specific treatment.  
**Protection of first-aiders** No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

# SAFETY DATA SHEET

United States



Version 3.0; January 11, 2019

---

## Section 5. Fire-fighting measures

### Extinguishing media

**Suitable extinguishing media**

Use an extinguishing agent suitable for the surrounding fire.

**Specific hazards arising from the chemical**

In a fire or if heated, a pressure increase will occur and the container may burst.

**Special protective actions for fire-fighters**

Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

**Special protective equipment for fire-fighters**

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

---

## Section 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

**For Mebrofenin before reconstitution:** To collect non-radioactive spills, use HEPA filtered vacuum or wet mop. Do not generate dust. Dispose of material as non-hazardous waste.

**For Mebrofenin Reconstituted with Sodium Pertechnetate Tc-99m:** If any loss or release of the radioactive contents occurs, notify your Radiation Safety Officer. All cleanup operations should be performed according to the Standard Operating Procedures (SOP) for radiation protection established for your facility and by the NRC, or other applicable local, provincial, state or federal regulations.

---

## Section 7. Handling and storage

### Precautions for safe handling

**Protective measures**

Put on appropriate personal protective equipment (see Section 8).

**Advice on general occupational hygiene**

Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

**Conditions for safe storage, including any incompatibilities**

Keep container in a dark place. Do not store or consume food, drink or tobacco in areas where they may become contaminated with this material. Store at controlled room temperature (20 - 25 °C).

**For Mebrofenin reconstituted with Sodium Pertechnetate Tc-99m**

The shielded vial should be stored at or below room temperature but do not freeze. Refer to the package insert for specific approved storage temperatures after reconstitution. Handling devices such as syringe shields and tongs should be used. Storage and disposal of the reconstituted, radioactive product should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorised to license the use of this radionuclide.

# SAFETY DATA SHEET

United States



Version 3.0; January 11, 2019

## Section 8. Exposure controls/personal protection

### Control parameters

#### Occupational exposure limits

Airborne Exposure Limits	OSHA Permissible Exposure Limit (PEL)	ACGIH® Threshold Limit Value (TLV®)
Stannous Flouride (0.73 mg/vial)	2 mg/m <sup>3</sup> (TWA), as Sn	2 mg/m <sup>3</sup> (TWA), as Sn

TWA = Time Weighted Average

For Tc-99m: NRC occupational concentration limit is 6 x 10E-3 µCi/mL of air.

#### Appropriate engineering controls

Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

#### Environmental exposure controls

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

#### Individual protection measures

##### Engineering Controls:

Not expected to require any special ventilation.

##### Eye/face protection:

Safety glasses with side-shields.

##### Skin protection:

Wear protective gloves and clean body-covering clothing.

##### Respiratory protection:

Not expected to require personal respirator usage

## Section 9. Physical and chemical properties

### Appearance

Physical state	Lyophilized solid.
Color	White.
Odor	Odorless.
Odor threshold	Not available.
pH	5.2 +/- 2 before lyophilization.
Melting point	ca. 0 °C (32 °F) reconstituted
Boiling point	ca. 100 °C (212 °F) reconstituted
Flash point	Not applicable.
Burning time	Not applicable.
Burning rate	Not applicable.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Lower and upper explosive(flammable) limits	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility	Soluble
Solubility in water	Soluble
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

## Section 10. Stability and reactivity

### Reactivity

No specific test data related to reactivity available for this product or its ingredients.

### Chemical stability

The product is stable.

### Possibility of hazardous reactions

Under normal conditions of storage and use, hazardous reactions will not occur.

### Conditions to avoid

No specific data.

### Incompatible materials

No specific data.

### Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

# SAFETY DATA SHEET

United States



Version 3.0; January 11, 2019

## Section 11. Toxicological information

The product is contained within an hermetically sealed glass serum vial and direct exposure is not likely to occur under normal handling and using the precautions described. Unusual events may lead to exposure through skin or eye contact. The information below pertains to the individual ingredients found in this product.

### Information on toxicological effects

#### Acute toxicity:

#### Toxicological Information for Active Ingredients:

LD/LC50 values that are relevant for classification:		
<b>78266-06-5 Mebrofenin</b>		
	LD50 iv	213.8 g (Iodine) /kg (Mouse) 226.4 mg/kg (Rat)
<b>1310-73-2 Sodium Hydroxide</b>		
Oral	LD50	2000 mg/kg (Rat)
<b>99-76-3 Methylparaben</b>		
Oral	LD50	6000 mg/kg (Rabbit)
<b>7647-01-0 Hydrochloric acid</b>		
Oral	LD50	900 mg/kg (Rabbit)
<b>94-13-3 Propylparaben</b>		
Oral	LD50	6332 mg/kg (Mouse)

#### 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.

#### Single Exposure (STOT - SE):

No further relevant information available

#### Repeated Exposure (STOT - RE):

No further relevant information available

**Carcinogenicity:** When this kit is reconstituted with Sodium Pertechnetate Tc-99m, this product contains a substance known to the State of California to cause cancer.

## Section 12. Ecological information

#### Toxicity

Not available.

#### Persistence and degradability

Not available.

#### Bioaccumulative potential

Not available.

#### Mobility in soil

#### Soil/water partition coefficient (KOC)

Not available.

#### Other adverse effects

No known significant effects or critical hazards.

# SAFETY DATA SHEET

United States



Version 3.0; January 11, 2019

---

## Section 13. Disposal considerations

### Disposal methods

The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

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

---

## Section 14. Transport information

Product is not regulated as dangerous goods for transport.

---

## Section 15. Regulatory information

### CERCLA Reportable Quantities:

When this kit is reconstituted with radioactive material, the Reportable Quantity for Tc-99m = 100 Ci (3.7 E 12 Bq)  
Releases to air, land or water of these hazardous substances which exceed the Reportable Quantity (RQ) must be reported.

### SARA Title III

302 Extremely Hazardous Substances: None

311/312 Hazard Categories: None

313 Toxic substances subject to annual release reporting requirements: None

RCRA Hazardous Waste Status: Non-hazardous (See Section 13 for additional details.) California Proposition 65: Warning

When this kit is reconstituted with radioactive material, this product contains a substance known to the State of California to cause cancer.

---

## Section 16. Other information

This document pertains, in most part, to the non-radioactive, non-reconstituted, lyophilized product. Once reconstituted with radioactive <sup>99m</sup>Tc, the material falls under the regulation of the MRCP, NRC, or other local, provincial, state, or federal agencies. Only trained professionals in licensed facilities are permitted to handle the radioactive reconstituted product.

---

**DISCLAIMER:** This above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Pharmalucence shall not be held liable for any damage resulting from handling or from contact with the above material.