



## Material Safety Data Sheet

HEPATOLITE®

Revised 03-Jul-2008  
Issued 02-NOV-2006

### CHEMICAL PRODUCT/COMPANY IDENTIFICATION

#### Material Identification

Grade: Pharmaceutical Reagent

#### Tradenames and Synonyms

DISOFENIN (ACTIVE INGREDIENT)  
DISIDA  
HEPATOLITE KIT

#### Company Identification

##### MANUFACTURER/DISTRIBUTOR

**Pharmalucence, Inc.**  
10 DeAngelo Drive  
Bedford, MA 01730

#### PHONE NUMBERS

Product Information: 1-800-221-7554  
Medical Emergency: 781-275-7120

### COMPOSITION/INFORMATION ON INGREDIENTS

#### Components

<u>Material</u>	<u>CAS Number</u>	<u>%</u>
DISOFENIN		~97.1
STANNOUS CHLORIDE, DIHYDRATE	7772-99-8	~1.2-2.9

### HAZARDS IDENTIFICATION

#### Potential Health Effects

Only ~ 21 mg of materials are contained in each glass, septum-sealed vial, hence normal workplace handling of this product is not considered hazardous. The following information is provided for those circumstances where handling of this product in the workplace may result in uncontrolled exposure and dust generation.

The toxicity of disofenin (the major constituent) has not been characterized.

## STANNOUS CHLORIDE, DIHYDRATE

Material is extremely destructive to tissue of the mucous membranes and upper respiratory tract, eyes, and skin.

Inhalation may be fatal as a result of spasm, inflammation, and edema of the larynx and bronchi, chemical pneumonitis and pulmonary edema.

Symptoms of exposure may include burning sensation, coughing, wheezing, laryngitis, shortness of breath, headache, nausea and vomiting.

### Carcinogenicity Information

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

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### FIRST AID MEASURES

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#### First Aid

#### INHALATION

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

#### SKIN CONTACT

In case of contact, wash skin with soap and water. Call a physician. Wash contaminated clothing before reuse.

#### EYE CONTACT

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.

#### INGESTION

If swallowed, immediately give two glasses of water. Never give anything to an unconscious person. Call a physician.

#### Notes to Physicians

HEPATOLITE is indicated in the diagnosis of acute cholecystitis as well as to rule out the occurrence of acute cholecystitis in suspected patients with right upper quadrant pain, fever, jaundice, right upper quadrant tenderness and mass or rebound tenderness, but not limited to these signs and symptoms.

Itching at the site of injection progressing to erythema multiforme has been reported following single administration. Rare cases of chills and nausea have been reported with related compounds.

No specific antidote for this material has been identified. Treatment in case of overexposure should be supportive and symptomatic. If vomiting occurs prevent aspiration.

If ingested and the patient is conscious, induction of emesis may be indicated. Gastric lavage may be indicated if the patient is unconscious. An activated charcoal slurry may be used. To prepare, suspend 50 grams of activated charcoal in 400 mL of water in a plastic bottle and shake well. Orally administer 5 mL/kg, or 350 mL for an average adult (70 kg or 154 lbs.).

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## FIRE FIGHTING MEASURES

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### Flammable Properties

Not a fire or explosion hazard.

### Extinguishing Media

Water Spray, Foam, Dry Chemical, CO<sub>2</sub>.

### Fire Fighting Instructions

Evacuate personnel to a safe area. Keep personnel removed and upwind of fire. Wear self-contained breathing apparatus. Wear full protective equipment.

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## ACCIDENTAL RELEASE MEASURES

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### Safeguards (Personnel)

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean up.

### Spill Clean Up

Use HEPA filtered vacuum or wet mop. Do not generate dust.

### Accidental Release Measures

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 Technelite MSDS.

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## HANDLING AND STORAGE

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### Handling (Personnel)

Avoid breathing dust. Avoid contact with eyes, skin, or clothing. Wash thoroughly after handling. Wash clothing after use.

### Handling (Physical Aspects)

Do not generate dust.

### Storage

Keep container in a dark place. Store 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).

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## EXPOSURE CONTROLS/PERSONAL PROTECTION

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### Engineering Controls

Handle in a laboratory fume hood, or other suitably ventilated work area.

### Personal Protective Equipment

Wear safety glasses with side shields. Wear full face protection when judged that the possibility exists for eye and face contact.

Wear an appropriate NIOSH approved air purifying respirator or positive pressure air-supplied respirator in situations where a respirator is judged appropriate to prevent inhalation.

Wear impervious clothing such as gloves, lab coat, shoe covers, apron, or jumpsuit, as appropriate. Consult the site safety professional for additional guidance, as needed.

### Exposure Guidelines

#### Applicable Exposure Limits

##### HEPATOLITE

PEL (OSHA): None Established

TLV (ACGIH): None Established

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## PHYSICAL AND CHEMICAL PROPERTIES

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### Physical Data

Solubility in Water:	Soluble.
Form:	Lyophilized solid.
pH:	4-5 pre-lyophilized.

The HEPATOLITE kit for the preparation of Technetium Tc99m disofenin is supplied in kits of five or thirty vials, sterile and non-pyrogenic.

The contents of the vial are lyophilized and stored under nitrogen.

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## STABILITY AND REACTIVITY

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### Chemical Stability

Stable at normal temperatures and storage conditions.

### Incompatibility with Other Materials

None reasonably foreseeable.

### Decomposition

Decomposition will not occur if handled and stored properly.

### Polymerization

Polymerization will not occur.

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## TOXICOLOGICAL INFORMATION

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### Animal Data

The toxicity of disofenin (the major constituent) has not been characterized. Available toxicity information for stannous chloride, dihydrate is summarized.

### Oral Data

No information available.

### Ocular Data

No information available.

### Dermal Data

No information available.

### Inhalation Data

No information available.

### Intravenous Data

LDLo: 20 mg/kg (dog)

LD50: 7.8 mg/kg (rat)

### Reproductive Toxicity

Developmental fetal effects and reproductive effects were noted at very high doses which were toxic to the mother (3 gm/kg).

### Mutagenicity

'In vitro' testing showed some evidence of DNA damage in hamster ovaries and in human leukocytes.

LD50 is the median dose at which lethality occurred in 50% of the animals tested following exposure by injection.

LDLo is the lowest dose at which lethality was noted following exposure by injection.

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## DISPOSAL CONSIDERATIONS

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### Waste Disposal

Treatment, storage, transportation, and disposal must be in accordance with applicable Federal, State/Provincial, and Local regulations.

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 Technelite MSDS.

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TRANSPORTATION INFORMATION

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Shipping Information

The known properties of this material do not constitute a hazard as defined by the U.S. Department of Transportation.

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OTHER INFORMATION

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NFPA, NPCA-HMIS

NFPA Rating

Health:	2
Flammability:	0
Reactivity:	0

NPCA-HMIS Rating

Health:	2
Flammability:	0
Reactivity:	0

The data in this Material Safety Data Sheet relates only to the specific material designated herein and does not relate to use in combination with any other material or in any process.

End of MSDS