

Product Name: PANHEMATIN®
Issued: Nov-09-2005



MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name and Address:

Manufactured by:
Abbott Laboratories
North Chicago, IL 60064, U.S.A.

Under contract to:
Hospira, Inc.
Lake Forest, IL 60045 U.S.A.

For:
Ovation Pharmaceuticals, Inc.
Deerfield, IL 60015, U.S.A.

Customer Service Telephone: 1 800 455 1141 (Panhematin)

Emergency Telephone: 1 (800) 424-9300 CHEMTREC (USA)
1 (703) 527 3887 CHEMTREC (INTERNATIONAL)

Product Name: PANHEMATIN®

Synonyms: Hemin for Injection

Product Use: Treatment of porphyrias.

National Drug Code Number: 67386-701-54

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Percent	OSHA PEL	ACGIH TLV	AIHA WEEL	Abbott EEL	Skin Notation
Hemin 15489-47-1	37.8	Not Listed	Not Listed	Not Applicable	0.5 mg/m ³ TWA for Hematin	None
Sodium Carbonate 497-19-8	26	Not Listed	Not Listed	Not Applicable	Not Applicable	None
Sorbitol 50-70-4	36.2	Not Listed	Not Listed	Not Applicable	Not Applicable	None

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Notes: OSHA PEL: US Occupational Safety and Health Administration- Permissible Exposure Limit.
ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value.
AIHA WEEL: American Industrial Hygiene Association - Workplace Environmental Exposure Level.
Abbott EEL: Abbott Laboratories Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.
C: Ceiling Limit.

Abbott : Hazardous per OSHA criteria

3. HAZARDS IDENTIFICATION

Emergency Overview:

Black crystalline powder in vial
Odor: Not determined.
May cause eye and skin irritation.

Routes of Exposure:

Oral: Not determined.
Dermal: Not determined.
Inhalation: Yes

Hazard Information:

Ingestion Rating: Not determined.
Skin Absorption Rating: Not determined.
Inhalation Rating: Possible Irritant.
Corrosiveness Rating: Not determined.
Skin Contact Rating: Possible Irritant.
Skin Sensitization Rating: Not determined.
Eye Contact Rating: Possible Irritant.
Target Organs: Bone Marrow , Kidney , Cardiovascular System , Eyes , Digestive System , Respiratory System .

Carcinogenicity Rating:

Ingredients	Percent	OSHA:	NTP:	IARC:	ACGIH:
Hemin	37.8	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Carbonate	26	Not Listed	Not Listed	Not Listed	Not Listed
Sorbitol	36.2	Not Listed	Not Listed	Not Listed	Not Listed

NFPA Rating:

Health: 2 (based on component)
Fire: 1
Reactivity: 0

Signs and Symptoms:

No signs and symptoms from occupational exposure are known. Clinical data suggests the following: changes in blood clotting, fever, variable cardiovascular system effects, abnormal kidney function. Components may cause: eye irritation, respiratory irritation, skin irritation, diarrhea.

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Medical Conditions Aggravated by Exposure: No medical conditions aggravated by occupational exposure are known. Clinical data suggests any pre-existing ailments of the following organs: hematopoietic system, kidney, eyes, skin, respiratory system, gastrointestinal system, cardiovascular system.

4. FIRST AID MEASURES

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

FLAMMABILITY:

Lower Explosive Limit: Not determined.
Autoignition Temp. (°C): Not determined.

FIRE-FIGHTING INFORMATION:

Suitable Extinguishing Media: Use appropriate medium for the underlying cause of the fire.

Special Exposure Hazards: Avoid inhalation of combustion products.

Explosivity: Fine dust clouds may form explosive mixtures with air.

6. ACCIDENTAL RELEASE MEASURES

Methods of Cleaning and Collecting: Recover product. Place into appropriate container for disposal. Clean area with suitable cleaning materials. Dispose of as directed in Section 13.

Personal Precautions: Avoid skin/eye contact. Use personal protective equipment identified in Section 8.

Environmental Precautions: Not determined.

7. HANDLING AND STORAGE

Handling: Handle according to label instructions.

Storage: Store according to label instructions.

Special Precautions: Not applicable.

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: Use in a well ventilated area.

Respiratory Protection: An approved respirator (i.e. NIOSH, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Wear eye protection appropriate to handling activities.

Gloves: Impervious gloves.

Other PPE Data: Not determined.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Black crystalline powder in vial

Odor: Odor: Not determined.

Boiling Pt. @ 760 mm Hg (°C): Not determined.

Melting/Freezing Point: Not determined.

Vapor Pressure (mm Hg) Not determined.

Bulk Density at 20°C: Not determined.

Solubility: Not determined.

Specific Gravity: Not determined.

pH: 8.0 - 9.5 , for the reconstituted product.

Viscosity (centipoise): Not determined.

10. STABILITY AND REACTIVITY

Chemical Stability: Stable from a safety point of view.

Self-Heating Tendency: Not determined.

Materials to Avoid: Not determined.

Hazardous Decomposition Products: Not determined.

Hazardous Polymerization: Not known to occur.

Conditions to Avoid: Not determined.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Oral: Data for component (s) given below.

Ingredients	Percent	Acute Test	Value	Units	Species
Sodium Carbonate	26	LD50 =	4090 6600	mg/kg mg/kg	Rats Mice
Sorbitol	36.2	LD50 =	15900-17800	mg/kg	Rats Mice

Acute Toxicity - Dermal: Not determined.

Acute Toxicity - Inhalation: Data for component (s) given below.

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Ingredients	Percent	Test	Value	Units	Species
Sodium Carbonate	26	LC 50 =	2.3 1.2 0.8	mg/L mg/L mg/L	Rats Rat (Male) Mice Guinea Pigs

Corrosivity: Not determined for product. One or more components - Corrosive to eyes.

Dermal Irritation: Not determined for product. One or more components - Produced mild skin irritation in rabbits.

Eye Irritation: Not determined for product. One or more components - Produced severe eye irritation in rabbits.

Sensitization: Not determined.

Target Organ Effects: In clinical use target organ effects include: blood, kidneys, cardiovascular system.

Hematin is a heme derived hemoglobin that controls hemoglobin synthesis. In clinical use, hematin has altered blood coagulation, kidney function and cardiovascular function.

Reproductive Effects: Not determined.

Carcinogenicity: Not determined.

Mutagenicity: Not determined.

Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

12. ECOLOGICAL INFORMATION

Aquatic Toxicity: Not determined.

Biodegradation: Not determined.

General Notes: Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods: All waste must be packaged, labeled, transported and disposed of in conformance with applicable local, state, and federal laws and regulations and in accordance with good engineering practices.

14. TRANSPORT INFORMATION

DOT/ADR:

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Status: Not Regulated.

ICAO/IATA:
Status: Not Regulated.

IMDG:
Status: Not Regulated.

TDG (Canada):
Status: Not Regulated.

15. REGULATORY INFORMATION

SARA 313 Information

Ingredients	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Hemin	37.8	No	Not Applicable	Not applicable
Sodium Carbonate	26	No	Not Applicable	Not applicable
Sorbitol	36.2	No	Not Applicable	Not applicable

SARA 311/312 Hazard Categories:

Immediate Health: Yes
Delayed Health: No
Fire: No
Sudden Pressure: No
Reactivity: No

TSCA Inventory Status: Exempt.

CERCLA Status: Not regulated.

RCRA Status: Not a hazardous waste.

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

EC HAZARD CLASSIFICATION:

Category of Danger: Exempt.
Indication of danger: Xi - Irritant.

Risk Phrases: R36 - Irritating to eyes.
ICH Classification: Not determined.

CANADIAN REGULATIONS:

Canadian Inventory: Not determined.
Canadian NDSL: Not determined.
WHMIS Hazard Class: Not determined.

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Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

16. OTHER INFORMATION

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