

	Sagent Pharmaceuticals, Inc.				
	Heparin Sodium Injection, USP			Material Safety Data Sheet (MSDS)	
	Issue Date: Feb 9, 2009	MSDS No.: MSDS 016	Version No.: 1.0	Form Number: R-SOP-009-F001	Page: 1 of 8

Section 1 - Chemical Product and Company

Distributor:

Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600

Emergency Telephone: 866-625-1618

Product Identifier:

Heparin Sodium Injection, USP

Product Code:

NDC 25021-400-01	NDC 25021-400-10
NDC 25021-400-30	NDC 25021-401-02
NDC 25021-402-01	NDC 25021-402-10
NDC 25021-403-01	NDC 25021-403-04
NDC 25021-404-01	

Common/Trade Name:

Heparin Sodium

Chemical Name:

(1) α -L-iduronic acid 2-sulfate, (2) 2-deoxy-2-sulfamino- α -D-glucose 6-sulfate, (3) β -D-glucuronic acid, (4) 2-acetamido-2-deoxy- α -D-glucose and (5) α -L-iduronic acid

Chemical Family:

Anticoagulant

Product Use:

Pharmaceutical

Product Type:

Regulated Prescription Drug

Container Information:

Vials

Section 2 - Composition / Information on Ingredients

Ingredient	mg/mL	CAS No.
Heparin Sodium	See Package Insert	9041-08-1
Sodium Chloride	See Package Insert	7647-14-5
Benzyl Alcohol*	0.1	100-51-6
Hydrochloric Acid	q.s. for pH adjustment	7674-01-0
Sodium Hydroxide	q.s. for pH adjustment	1310-73-2
Water for Injection	q.s. to 1mL	7732-18-5

*Product code 401-02 is preservative-free and does not contain benzyl alcohol.

Section 3 - Hazards Identification

Primary Physical and Health Hazards:

Heparin sodium is not expected to be active orally. Effects of exposure by injection may include delayed clotting of blood. Dilute solutions of benzyl alcohol are not expected to be irritating.

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Routes of Entry: Inhalation, eye/skin contact or ingestion

Chemical Listed as Carcinogen: **NTP:** No **IARC:** No **OSHA:** No

Medical Conditions Generally Aggravated by Exposure: Individuals with documented hypersensitivity to heparin sodium and individuals with thrombocytopenia or increased risk for hemorrhage may show symptom to exposure.

Section 4 - First Aid Measures

Eye Exposure: Flush eyes with large volumes of water for 15 minutes or more. Seek medical attention if irritation or signs of exposure are noted.

Skin Exposure: Remove contaminated clothing immediately. Flush area with water for at least 15 minutes. Seek medical attention.

Ingestion: Flush mouth out with water, immediately seek medical attention.

Injection: In cases of accidental injection, wash and disinfect area, seek medical attention.

Inhalation: Move exposed subject to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.

Notes to Physician: See patient package insert in shipping carton for complete information.

Section 5 - Fire Fighting Measures

Flash Point Not Applicable

Autoignition Temperature: Not Applicable

Flammable Limits in Air Lower %: Not Established
Upper %: Not Established

Flammable Limits: Not Established

Extinguishing Media Water spray, dry chemical, carbon dioxide, or foam as appropriate to surroundings.

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Special Fire Fighting Procedures: Wear self-contained breathing apparatus and protective clothing.

Unusual Fire/Explosion Hazards: None established

Section 6 - Accidental Release Measures

Spill: Wear recommended personal protective equipment (See Section 8 – Exposure Controls/Personal Protection). Use absorbent towels or pads to clean up spill. Wipe surface clean with soap and water.

Release to Air: If aerosolized, reduce exposure by ventilating area. Clean up immediately.

Release to Water: Refer to local and regional water authority requirements.

Section 7 - Handling and Storage

General Handling: When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.

Waste Disposal Method: Dispose of waste in accordance with all applicable Federal, State and local laws.

Storage Conditions: Store at 20° to 25°C (68°F to 77°F) [see USP Controlled Room Temperature].

Section 8 - Exposure Controls / Personal Protection

Respiratory Protection: With satisfactory ventilation, respiratory protection is usually not required.

Eye Protection: Safety glasses

Ventilation: Handle product in a well ventilated area.

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Skin Protection: Disposable garments if direct skin contact is anticipated

Other Protective Equipment: Protective Latex or Nitrile gloves

Additional Exposure Precautions: None established

Exposure Limits

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Heparin Sodium (porcine intestinal mucosa)	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Sodium Chloride	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Benzyl Alcohol	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Water for Injection	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

Section 9 - Physical and Chemical Properties

Physical State:	Liquid	Specific Gravity:	Not Available
Appearance:	Clear, colorless to slightly yellow solution	Evaporation Rate:	Not Available
Boiling Point:	Not Available	Solubility in Water:	Soluble
Vapor Pressure:	Not Available	pH:	5.0 – 7.5
Vapor Density:	Not Available	Molecular Weight	Variable

Section 10 - Stability and Reactivity

Stability: Stable at normal temperature and pressure

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**Incompatibility
(Materials to
avoid):** Not established

**Hazardous
Decomposition:** Not established

**Hazardous
Polymerization:** Will not occur

**Conditions to
Avoid:** Do not allow to freeze.

Section 11 - Toxicological Information

**Signs & Symptoms
of Exposure &
Overexposure:** This product is intended for therapeutic use only when prescribed by a physician. Adverse reactions from prescribed doses include: hemorrhage, local irritation, erythema, mild pain, hematoma, ulceration, hypersensitivity reactions (chills, fever, urticaria), asthma, rhinitis, lacrimation, headache, nausea, vomiting, anaphylactic reactions including shock, itching, burning and thrombocytopenia. The chief sign of heparin overdose is bleeding (nosebleeds, blood in urine, tarry stools, easy bruising, or petechial formations). When clinical circumstances require reversal of heparinization, protamine sulfate should be administered. Occupational exposure has not been fully investigated.

Acute Toxicity

Component	Type	Route	Species	Dosage
Heparin Sodium (porcine intestinal mucosa)	LD ₅₀	Oral	Rat	4869 mg/kg
Heparin Sodium (porcine intestinal mucosa)	LD ₅₀	Oral	Mouse	>5 gm/kg
Heparin Sodium (porcine intestinal mucosa)	LD ₅₀	IV	Rat	2449 mg/kg

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Heparin Sodium (porcine intestinal mucosa)	LD ₅₀	IV	Mouse	2800 mg/kg
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Section 12 - Ecological Information

Information is currently not available on the environmental impact of Heparin Sodium. Handle in a manner to prevent spills or releases to the environment.

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any clean up materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations

TSCA - Yes

CERCLA - *Not on this list*

SARA 302 - *Not on this list*

SARA 313 - *Not on this list*

Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief

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that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
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Glossary: This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)