
	Sagent Pharmaceuticals, Inc.				
	Heparin Sodium Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Sep 25, 2014	SDS No.: SDS 016	SDS Version No.: 2.0	Form No.: R-SOP-009-F001	Page: 1 of 9

Section 1 - Identification

- (a) **Product Identifier:** Heparin Sodium Injection, USP
- (b) **Product Code:** 25021-400, 25021-401, 25021-402, 25021-403, 25021-404
- 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
- (c) **Product Use:** Pharmaceutical
- Product Type:** Regulated Prescription Drug
- Container Information:** Vials
- (d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 700, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618

Section 2 - Hazards Identification

- (a) **Classification:**
- HMIS Rating**
- | | |
|-----------------|---|
| Health Hazard | 0 |
| Flammability | 0 |
| Physical Hazard | 0 |
- NFPA Rating**
- | | |
|-------------------|---|
| Health Hazard | 0 |
| Fire Hazard | 0 |
| Reactivity Hazard | 0 |

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(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
<u>Precautionary Statements:</u> P260 P305 + P351 + P338 P337 + P313 P264 P314	<ul style="list-style-type: none"> - Do not breathe dust/fume/gas/mist/vapors/spray - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. - If eye irritation persists, get medical attention. - Wash hands after handling. - Get medical attention if you feel unwell

(d) Unknown Acute Toxicity: N/A

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
(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	Heparin Sodium	See Package Insert	9041-08-1	N/A
Sodium Chloride	Sodium Chloride	See Package Insert	7647-14-5	N/A
Benzyl Alcohol*	Benzyl Alcohol*	0.1% (v/v)	100-51-6	N/A
Hydrochloric Acid	Hydrochloric Acid	q.s. for pH adjustment	7674-01-0	N/A
Sodium Hydroxide	Sodium Hydroxide	q.s. for pH adjustment	1310-73-2	N/A
Water for Injection	Water for Injection	q.s. to 1mL	7732-18-5	N/A

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

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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

- (a) **Extinguishing Media** Water spray, dry chemical, carbon dioxide, or foam as appropriate to surroundings.
- (b) **Hazardous Combustion Products:** None established
- (c) **Special Protective Equipment / Precautions:** Wear self-contained breathing apparatus and protective clothing.

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.

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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.

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

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits


Compound	Issuer	Type	Exposure Limit
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

(b) Engineering Controls

Ventilation: Handle product in a well ventilated area.

(c) Individual Protection Measures

Respiratory Protection:	With satisfactory ventilation, respiratory protection is usually not required.
Eye Protection:	Safety glasses
Skin Protection:	Disposable garments if direct skin contact is anticipated

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Other Protective Equipment:	Protective Latex or Nitrile gloves
Additional Exposure Precautions:	None established

Section 9 - Physical and Chemical Properties

(a)	Appearance	Clear, colorless to slightly yellow solution
(b)	Odor	Not established
(c)	Odor Threshold	Not established
(d)	pH	5.0 – 7.5
(e)	Melting Point:	Not applicable
(f)	Initial Boiling Point:	Not Available
(g)	Flash Point	Not applicable
(h)	Evaporation Rate:	Not Available
(i)	Flammability	Not applicable
(j)	Upper Lower Flammability or Explosion Limits	Not applicable
(k)	Vapor Pressure:	Not Available
(l)	Vapor Density:	Not Available
(m)	Relative Density	1.01 to 1.039 at 25°C
(n)	Solubility(ies)	Soluble in water
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not applicable
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

(a)	Reactivity	No reactivity hazards known
(b)	Chemical Stability	Stable at normal temperature and pressure

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(c)	Possibility of Hazardous Reactions	Not established
(d)	Conditions to Avoid	Do not allow to freeze.
(e)	Incompatible Materials	Not established
(f)	Hazardous Decomposition Products	NO _x , Na ₂ O. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Inhalation, eye/skin contact or ingestion
(b)	Symptoms related to the physical, chemical and toxicological characteristics	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.
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	Individuals with documented hypersensitivity to heparin sodium and individuals with thrombocytopenia or increased risk for hemorrhage may show symptom to exposure.

(d) 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
Heparin Sodium (porcine intestinal mucosa)	LD ₅₀	IV	Mouse	2800 mg/kg

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(e) Hazardous Chemical Listings

NTP: No

IARC: No

OSHA: No

Section 12 - Ecological Information


(a) Ecotoxicity	<u>Sodium Chloride</u> Water flea (<i>Daphnia magna</i>), EC50 48hrs, 340.7 – 469.2 mg/L American eel (<i>Anguilla rostrata</i>), LC50 96hrs, 0 – 27260 mg/L
(b) Persistence and degradability	Information is currently not available on the environmental impact of Heparin Sodium.
(c) Bioaccumulative potential	Information is currently not available on the environmental impact of Heparin Sodium.
(d) Mobility in soil	Information is currently not available on the environmental impact of Heparin Sodium.
(e) Other Adverse Effects	Information is currently not available on the environmental impact of Heparin Sodium.

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

(a) UN Number	Not Regulated
(b) UN Proper Shipping Name	Not Regulated
(c) Transport Hazard Class(es)	Not Regulated
(d) Packing Group	Not Regulated
(e) Environmental Hazards	Not Regulated
(f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not Regulated
(g) Special Precautions	Not Regulated

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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

California Proposition 65 – Not listed

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 that it is accurate. THIS 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 SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice

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CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
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
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
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
SDS	Safety Data Sheet
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)
WHMIS	Workplace Hazardous Materials Information System