Heparin Sodium Injection

Effective Date: 18-Oct-2002

Eli Lilly and Company
Material Safety Data Sheet

Section 1 - Chemical Product and Company

Manufacturer:
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Manufacturer's Emergency Phone:
1-317-276-2000
CHEMTREC:
1-800-424-9300 (North America)
1-703-527-3887 (International)

Common Name: Heparin Sodium Injection

Chemical Name: Heparin sodium salt
Synonym(s): Heparina Sodica Formulation; 017265 Formulation; Heparin Sodium Formulation; Heparin Injection
Trademarks(s): Ariven
Lilly Item Code(s): AM0405; AM0520; AM0622; AM0642; VL0405; VL7323

See attached glossary for abbreviations.

Section 2 - Composition / Information on Ingredients

Ingredient	CAS	Concentration %
Heparin Sodium	9041-08-1	0.7 - 15
Benzyl Alcohol	100-51-6	1
Water	7732-18-5	84 - 98

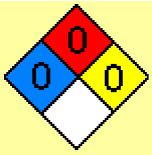
Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

Exposure Guidelines:
Benzyl alcohol - WEEL 10 ppm (44.2 mg/m3) TWA.

Section 3 - Hazards Identification

Appearance: Clear aqueous solution
Physical State: Liquid
Odor: Odorless

Emergency Overview



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Lilly Laboratory Labeling Codes:
Health 0 **Fire** 0 **Reactivity** 0

Primary Physical and Health Hazards: Not Considered a Health Hazard.

Caution Statement: Heparin Sodium Injection is not considered to be a health hazard.

Routes of Entry: Inhalation and skin contact.

Effects of Overexposure: 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.

Medical Conditions Aggravated by Exposure: Hemophilia and individuals on coumadin, heparin, or other anticoagulant therapy.

Carcinogenicity: Heparin sodium - No carcinogenicity data found. Not listed by IARC, NTP, ACGIH, or OSHA.
Benzyl alcohol - Not listed by IARC, NTP, ACGIH, or OSHA. Two-year carcinogenicity studies conducted by NTP demonstrated no evidence of carcinogenicity in mice and rats.

Section 4 - First Aid Measures

Eyes: Flush eyes with plenty of water. Get medical attention.

Skin: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops.

Inhalation: Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

Ingestion: Do not induce vomiting. Call a physician or poison control center. If available, administer activated charcoal (6-8 heaping teaspoons) with two to three glasses of water. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

Section 5 - Fire Fighting Measures

Flash Point: No applicable information found
UEL: No applicable information found

LEL: No applicable information found

Extinguishing Media: Use water, carbon dioxide, dry chemical, foam, or Halon.

Unusual Fire and Explosion Hazards: None known.

Hazardous Combustion Products: May emit toxic fumes when exposed to heat or fire.

Section 6 - Accidental Release Measures

Spills: Prevent further migration into the environment. Use absorbent/adsorbent material to solidify liquids. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).

Section 7 - Handling and Storage

Storage Conditions: Controlled Room Temperature: 15 to 30 C (59 to 86 F).

Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information.

Under normal use and handling conditions, no protective equipment is required. The following is recommended for a production setting:

Respiratory Protection: Use an approved respirator.

Eye Protection: Chemical goggles and/or face shield.

Ventilation: Laboratory fume hood or local exhaust ventilation.

Other Protective Equipment: Chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

Section 9 - Physical and Chemical Properties

Appearance: Clear aqueous solution
Odor: Odorless
Boiling Point: No applicable information found
Melting Point: Not applicable
Specific Gravity: No applicable information found
pH: 5.0 to 7.5
Evaporation Rate: No applicable information found
Water Solubility: Soluble
Vapor Density: No applicable information found

Vapor Pressure: No applicable information found

Section 10 - Stability and Reactivity

Stability: Stable at normal temperatures and pressures.

Incompatibility: May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.).

Hazardous Decomposition: May emit toxic fumes when heated to decomposition.

Hazardous Polymerization: Will not occur.

Section 11 - Toxicological Information

Acute Exposure

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

Oral: Heparin sodium - Mouse, median lethal dose greater than 5000 mg/kg.

Skin: No applicable information found.

Inhalation: No applicable information found.

Intravenous: Heparin sodium - Mouse, median lethal dose 2800 mg/kg.

Skin Contact:
Benzyl alcohol - Rabbit, irritant

Eye Contact: 30% Heparin solution - Rabbit, slight irritant
5% Heparin sodium solution - Rabbit, nonirritant
Benzyl alcohol - Rabbit, corrosive

Chronic Exposure

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

Target Organ Effects: Heparin - Blood effects (decreased red blood cell count, decreased hemoglobin).
Benzyl alcohol - Nervous system effects (nerve tissue change, staggered gait, drowsiness)

Reproduction: Heparin - Rats administered subcutaneous doses up to 10 mg/kg/day demonstrated no effects on conception or pregnancy or on teratogenicity, implantation sites, or fetal weight (when administered during organogenesis).
Benzyl alcohol - One study reported decreased fetal weight at maternally high doses. No developmental effects have been reported in other animal studies.

Sensitization:
Benzyl alcohol - Guinea pig, not a contact sensitizer.

Mutagenicity: Heparin - Negative in Ames assay. No increase in chromosome aberrations in human lymphocytes in vitro. Negative in rate bone marrow micronucleus test in vivo.
Benzyl alcohol - Not mutagenic in bacterial cells, inconclusive results in mammalian cells.

Section 12 - Ecological Information

No environmental data for the mixture or formulation. The environmental information for ingredient(s) or related material(s) are presented.

Ecotoxicity Data: Benzyl alcohol
Fathead minnow 96-hour median lethal concentration: 460 mg/L
Bluegill sunfish 96-hour median lethal concentration: 10 mg/L
Tidewater silverfish 96-hour median lethal concentration: 15 mg/L
Daphnia magna 48-hour median lethal concentration: 360 mg/L
Inland silverside 96-hour median lethal concentration: 15 mg/L
Green algae median effective concentration: 2600 mg/L

Environmental Fate: Benzyl alcohol
5-day Biological Oxygen Demand (acclimated microbial sludge): 70%
5-day Biological Oxygen Demand (sewage seed sludge): 48%
Bioconcentration factor: 4
Log Kow: 1.10

Environmental Summary: Benzyl alcohol - Slightly toxic to practically non-toxic in aquatic organisms.
Material is expected to be mobile in soil. Material is expected to biodegrade rapidly and is not expected to bioconcentrate in aquatic organisms.

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup 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 Eli Lilly and Company 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

Heparin sodium and benzyl alcohol
TSCA - Yes
CERCLA - Not on this list
SARA 302 - Not on this list
SARA 313 - Not on this list
OSHA Substance Specific - No

EU Regulations

EC Classification
Not assigned an overall EC classification.

Section 16 - Other Information

MSDS Sections Revised: MSDS Status.

Emergency Overview Sections Revised: Emergency Overview Status.

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 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:
Eli Lilly and Company
Hazard Communication
317-277-6029

For additional copies contact:
Eli Lilly and Company
1-800-LILLY-Rx (1-800-545-5979)

GLOSSARY:

ACGIH = American Conference of Governmental Industrial Hygienists
AIHA = American Industrial Hygiene Association

BEI = Biological Exposure Index
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
EC = European Community
EINECS = European Inventory of Existing Chemical Substances
ELINCS = European List of New Chemical Substances
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
IEG = Lilly Interim Exposure Guideline
IMO = International Maritime Organization
Kow = Octanol/Water Partition Coefficient
LEG = Lilly Exposure Guideline
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
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
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
STEG = Lilly Short Term Exposure Guideline
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
WEEL = Workplace Environmental Exposure Level (AIHA)