

Heparin in 50% Glycerol, USP

Revision Date 21-OCT-2024

Revision Number 1

1. Identification of the Substance/Mixture and the Company/Undertaking

Product Identifier

Product Name Heparin in 50% Glycerol, USP

Other means of identification

Product Code USP-HGS-050-10-VBP-1, USP-HGS-500-10-VB-1, USP-HGS-500-10-VBP-1, USP-HGS-500-10-VB-5, USP-HGS-500-10-VBP-5, USP-HGS-500-50-VB-1, USP-HGS-500-50-VBP-1.

Synonyms

Heparin Heparin sodium, Sodium heparin, Sodium acid heparin, Anti-coagulant
Glycerol Glycerin, Glycerine, 1,2,3-Propanetriol

Chemical Family Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Recommended use Anti-coagulant catheter lock solution for use in laboratory animal research only.

Restrictions on use Not for Human Use. This product contains no preservatives.

Details of the supplier of the safety data sheet:

Manufacturer Instech Laboratories, Inc.
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Plymouth Meeting, PA 19462
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INSTECH**Heparin in 50% Glycerol, USP****2. Hazard(s) Identification****Classification of Substance or Mixture**

GHS - Classification	Not classified as hazardous
Physical hazards	Not classified
Health hazards	Category 2B: May cause eye damage/eye irritation Category 3: May cause mild skin irritation.
OSHA defined hazards	Not classified
Label elements	Not classified

Physical Hazards

Explosives	No significant hazard
Flammable gases	Not applicable
Flammable aerosols	Not applicable
Oxidizing gases	Not applicable
Gases under pressure	Not applicable
Flammable liquids	Not applicable
Flammable solids	Not classified
Self-reactive substances and mixtures	Not applicable
Pyrophoric liquids	Not applicable
Pyrophoric solids	Not applicable
Self-heating substances and mixtures	Not applicable
Substances and mixtures which, in contact with water, emit flammable gases	Not applicable
Oxidizing liquids	Not applicable
Oxidizing solids	Not applicable
Organic peroxides	Not applicable
Corrosive to metals	Not applicable

Human Health Hazards

Acute toxicity (Oral)	Category 5; LD ₅₀ g/kg (very low)
Acute toxicity (Dermal)	Category 5; provisional (very low)
Acute toxicity (Inhalation: Gases)	Not applicable
Acute toxicity (Inhalation: Vapors)	Not applicable
Acute toxicity (Inhalation: Dusts)	Not applicable

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Acute toxicity (Inhalation: Mists)	Not applicable
Skin corrosion/irritation	Category 3, May cause mild skin irritation
Serious eye damage/eye irritation	Category 2B, May cause eye damage/eye irritation
Respiratory sensitization	No data available
Skin sensitization	Category 3, May cause mild skin irritation
Germ cell mutagenicity	No data available.
Carcinogenicity	No data available.
Reproductive toxicity	No data available.
Aspiration hazard	No data available.

Environmental Hazards

Acute toxicity to aquatic environment	No data available.
Chronic toxicity to the aquatic environment	No data available.

3. Composition/information on ingredients

Substance

Hazardous Ingredients	CAS#	EC#	GHS Classification	%
N/A	N/A	N/A	N/A	N/A

Ingredients	CAS#	EC#	GHS Classification	%
Heparin Sodium, USP	9041-0-1	9041-08-1	Not Listed	*
Water for Injection, USP Sterile Grade	7732-18-5	231-791-2	Not Listed	*
Glycerin, Natural, USP	56-81-5	200-289-5	Not Listed	50%

Additional Information

* The exact percentage (concentration) of composition corresponds with the label on product.

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4. First Aid Measures

Description of first aid measures

General advice	Description of necessary measures, subdivided according to the different routes of exposure, i.e., inhalation, skin and eye contact and ingestion. First aid measures are not specific for Heparin in 50% Glycerol, USP and do not imply that toxicity from the material is expected. If you feel respiratory symptoms or are unwell after exposure to Heparin in 50% Glycerol, USP see a physician. Serious health should always be investigated because heparin alone is unlikely to cause these symptoms other than cough if inhaled, or if ingested or applied to skin.
Inhalation	Move exposed individual to fresh air. Loosen clothing as necessary and position individual in a comfortable position. See medical advice if discomfort or irritation persists. If breathing is difficult, give oxygen.
Ingestion	Heparin is expected to be broken down rapidly in the stomach. Ingestion of large amounts might induce nausea and vomiting as a nonspecific effect. Treat symptomatically and obtain medical attention if required. Follow general measures for ingestion of foreign substances: Do not induce vomiting. Call a physician or a poison control center. Do not give anything by mouth to an unconscious person.
Skin	Take off contaminated clothing and shoes immediately. Wash affected area with soap and water. Clean contaminated clothing by washing before reuse. Seek medical attention if irritation or discomfort persists.
Eye	Protect unexposed eye. Rinse/flush exposed eye(s) gently using water for 15-20 minutes. Remove contact lenses if needed. Immediately get medical assistance.

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. Fire Fighting Measures

Suitable Extinguishing Media As for primary cause of fire. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Special Hazards Arising from the Substance or Mixture

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Hazardous combustion Products	May produce toxic fumes of nitrogen, sulfur oxides, carbon dioxide, and carbon monoxide during fires.
Unsuitable extinguishing media	No data available
Specific hazards arising from the chemical	No data available
Explosion data	No data available
Explosive limits	No data available
Sensitivity to mechanical impact	No data available
Sensitivity to static discharge	No data available
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental Release Measures

Personal precautions, protective equipment, and emergency procedures

Personal precautions	Ensure adequate ventilation. Avoid contact with skin, eyes, or clothing. Use personal protective equipment as required.
Other Information	Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so
Methods for cleaning up	Follow facility-specific procedures for spill response. When cleaning spills, wear appropriate personal protective equipment. Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

7. Handling and Storage

Precautions for safe handling

Advice on safe handling	Do not handle until all safety precautions have been read. Do not eat, drink, or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection. Avoid contact with eyes, skin, and clothing.
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Wash hands thoroughly after handling.
 Releases to the environment should be avoided.
 Wash contaminated clothing before reuse.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store in a cool, dry place 15°C-25°C (59°F-77°F)
 Separated from strong oxidants.
 Keep containers tightly closed in a dry, cool, and well-ventilated place.
 Protect from sunlight.
 Keep out of reach of children.
 Avoid excessive heat.
 Do not freeze.

8. Exposure Control/Personal Protection

Control Parameters

Exposure Limits

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Glycerin 56-81-5	10 mg/m ³ TWA 3 mg/m ³ TWA	15 mg/m ³ TWA 5 mg/m ³ TWA	No data available

Exposure control Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate.

Personal protection Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hand protection Impervious gloves (e.g., Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes / face protection Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin and body protection Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g., particulate respirator with a half mask, P3 filter).

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(Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

General hygiene considerations

Avoid contact with skin, eyes, or clothing.

9. Physical and Chemical Properties

Information on basic physical and chemical properties

Physical state	Aqueous solution
Visual appearance	Liquid
Color	Colorless
Odor	Odorless
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks / Method</u>
Molecular formula	Mixture	None known
Molecular weight	No data available	None known
Specific gravity	1.249 s.g.	None known
Solvent solubility	No data available	None known
Water solubility	No data available	None known
Solubility	Water	None known
Insoluble	No data available	None known
pH	5.0-7.5	None known
Freezing/Melting point (°C)	No data available	None known
Boiling point (°C)	No data available	None known
Decomposition temperature (°C)	No data available	None known
Evaporation rate (Gram/s)	No data available	None known
Vapor pressure (kPa)	No data available	None known
Vapor density (g/mL)	No data available	None known

10. Stability and Reactivity

Reactivity	No information available.
Chemical stability	Stable under recommended storage conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	No data available.
Incompatible materials	None known based on information supplied.

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Hazardous decomposition products	None known based on information supplied.
Chemically stability	Stable under normal conditions of use.
Incompatibility with other substances	As a precautionary measure, keep away from strong oxidizers. Heparin is incompatible with ethanol and should not be used with ethanol lock therapy.

11. Toxicological Information

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Category 2B, May cause eye irritation. May cause redness, itching, and pain.
Skin contact	Category 3, May cause mild skin irritation.
Ingestion	Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical, and toxicological characteristics

Symptoms	May cause redness and tearing of the eyes. Prolonged contact may cause redness and irritation.
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Acute toxicity

Numerical measures of toxicity

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Heparin Sodium, USP 9041-0-1	= >2 mg/kg (Rat)	Category 5	No data available
Glycerin 56-81-5	= 12600 mg/kg (Rat)	2190mg/kg (Rat)	No data available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	Category 3, May cause skin irritation. Classification based on data available for ingredients.
Serious eye damage/ eye irritation	May be irritating to eyes. Classification based on data available for ingredients.

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Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Target organ effects	Kidney, eyes, skin.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.
Known clinical effects	Clinical use of this drug has caused hemorrhage, gastrointestinal bleeding, increased bleeding time. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

12. Ecological Information

Environmental properties have not been investigated. Releases to the environment should be avoided.

Chemical Name	Algae/aquatic plants	Fish	Dermal LD50	Inhalation LC50
Glycerin 56-81-5	No data available	LC50: 51 - 57mL/L (96h, Oncorhynchus mykiss)	No data available	No data available

Persistence and degradability No information available.

Bioaccumulation No information available.

Other adverse effects

Heparin Highly biodegradable

Component Information

Chemical Name	Partition coefficient
Glycerin 56-81-5	-1.76

Other adverse effects

Heparin Highly biodegradable

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Glycerol No information available.

13. Disposal Considerations

Waste treatment methods

Waste from residues/unused products Waste must be disposed of in accordance with federal, state, and local environmental control regulations. Do not allow product to reach sewage system or open water. It is the responsibility of the waste generator to properly characterize all materials according to applicable regulatory entities.

Contaminated packaging Do not reuse empty containers.

14. Transport Information

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. Regulatory Information

International Inventories

TSCA

Heparin	Listed inventory
Glycerol	Complies

DSL/NDSL (EU)

Heparin	Not classified
Glycerol	Complies

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

US Federal Regulations

SARA 311/312 Hazard Categories	Not listed
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CERCLA	Not listed
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US State Regulations

California Proposition 65	Not listed
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U.S. State Right-to-Know Regulations Not listed

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other Information

Data Sources: Publicly available toxicity information. Instech Laboratories, Inc is proprietary drug development information.

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Instech Laboratories, Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document, there is no known information at this time.

17. Version History

Version History				
Version	Approved By	Revision Date	Description of Change	Author
0	JNewdeck	01-JUN-2022	N/A	Sterile Solutions Department
1	JNewdeck	21-OCT-2024	Added product codes USP-HGS-050-10-VBP-1, USP-HGS-500-10-VB-1, USP-HGS-500-10-VBP-1 to Section 1. Removed sodium hydroxide and hydrochloric acid buffers from Section 3.	Flush & Lock Solutions Department

End of Safety Data Sheet