

**SAFETY DATA SHEET**  
**Norepinephrine Bitartrate Injection**



## SECTION 1: IDENTIFICATION

### Product Identifier

Product Name : Norepinephrine Bitartrate Injection USP 4 mg/4 mL (1 mg/mL)  
Product Use : Human prescription drug. For intravenous infusion only.  
Supplier Details : Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA.  
Emergency Telephone Number : +91-4467901901/02/03

## SECTION 2: HAZARDS IDENTIFICATION

GHS-US/CA Classification : Not Classified.  
GHS-US/CA Labeling : No labeling applicable according to 29 CFR 1910.1200 and the Hazardous Products Regulations (HPR) SOR/2015-17  
Other Hazards : Exposure may aggravate pre-existing eye, skin, or respiratory conditions.  
Unknown Acute Toxicity (GHS-US/CA) : No data available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Substance	Not applicable	
Mixture		
Name	CAS Number	%*
Water	7732-18-5	98.99
Sodium Chloride	7647-14-5	0.8
Norepinephrine Bitartrate Monohydrate	108341-18-0	0.19
Sodium Metabisulfite	7681-57-4	0.02
*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%)		

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of first-aid measures

General : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).  
Inhalation : When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.  
Skin Contact : Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.

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- Eye Contact : Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.
- Ingestion : Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

**4.2. Most important symptoms and effects both acute and delayed**

- General : Not expected to present a significant hazard under anticipated conditions of normal use.
- Inhalation : Prolonged exposure may cause irritation.
- Skin Contact : Prolonged exposure may cause skin irritation.
- Eye Contact : May cause slight irritation to eyes.
- Ingestion : Ingestion may cause adverse effects.
- Chronic Symptoms : None expected under normal conditions of use.

**4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed**

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

**SECTION 5: FIRE FIGHTING MEASURES**

**5.1. Extinguishing media**

- Suitable Extinguishing Media : Water spray, fog, carbon dioxide (CO<sub>2</sub>), alcohol-resistant foam, or dry chemical.
- Unsuitable extinguishing media : Do not use a heavy water stream. Use of heavy stream of water may spread fire.

**5.2. Specific hazards arising from the Substance or Mixture**

- Fire Hazard : Not Flammable
- Explosion Hazard : Product is not explosive
- Reactivity : Hazardous reactions will not occur under normal conditions.

**5.3. Advice for firefighters**

- Precautionary Measures Fire : Exercise caution when fighting any chemical fire.
- Protection During Firefighting : Use water spray or fog for cooling exposed containers.
- Hazardous Combustion Products : None expected under normal conditions of use

**5.4. Reference to Other Sections**

Refer to Section 9 for flammability properties.

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

**6.1. Personal Precautions, Protective Equipment and Emergency Procedures**

- General Measures : Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray).

**6.1.1. For non-emergency personnel**

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Protective Equipment : Use appropriate personal protective equipment (PPE).

Emergency Procedures : Evacuate unnecessary personnel.

#### **6.1.2. For emergency personnel**

Protective Equipment : Equip cleanup crew with proper protection.

Emergency Procedures : Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

#### **6.2. Environmental Precautions**

Prevent entry to sewers and public waters.

#### **6.3. Methods and materials for containment and cleaning up**

For Containment : Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up : Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

#### **6.4. Reference to Other Sections**

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

### **SECTION 7: HANDLING AND STORAGE**

#### **7.1. Precautions for safe handling**

Precautions for Safe Handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray.

Hygiene Measures : Handle in accordance with good industrial hygiene and safety procedures.

#### **7.2 Conditions for Safe Storage, Including Any Incompatibilities**

Technical Measures : Comply with applicable regulations.

Storage Conditions : Keep container closed when not in use. Store in a dry, cool place. Keep/store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). [See USP Controlled Room Temperature.] Store in original carton until time of administration to protect from light.

Incompatible Materials : Strong acids, strong bases, strong oxidizers. Water reactive materials.

#### **7.3 Specific End Use(s)**

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Human prescription drug. For intravenous infusion only.

**SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION**

**Occupational Exposure Limits**

Compound	Exposure Limits		
	OSHA-PEL	ACGIH-TLV	AIHA WEEL
Norepinephrine Bitartrate	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

Engineering Controls : Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

**Personal Protective Equipment**

Respiratory Protection : If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Hand Protection : Wear protective gloves.

Eye and Face Protection : Chemical safety goggles.

Skin and Body Protection : Wear suitable protective clothing.

Other : When using, do not eat, drink or smoke.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

Appearance

Physical State : Liquid

Appearance : Colorless solution

Odor : Not available

Odor Threshold : Not available

pH : 3 – 4.5

Melting Point : Not available

Boiling Point : Not available

Flash Point : Not available

Freezing Point : Not available

Flammability (solid, gas) : Not applicable

Lower and Upper Explosive (flammable) limits : Not available

Vapour Pressure : Not available

Relative Vapor Density at 20°C : Not available

Relative Density : Not available

Specific Gravity : Not available

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Solubility	: Norepinephrine Bitartrate is freely soluble in water; slightly soluble in alcohol; practically insoluble in chloroform and in ether.
Partition Coefficient: n-octanol/water	: Not available
Viscosity	: Not available

## SECTION 10: STABILITY AND REACTIVITY

Reactivity	: Hazardous reactions will not occur under normal conditions.
Chemical Stability	: Stable under recommended handling and storage conditions.
Possibility of Hazardous Reactions	: Hazardous polymerization will not occur.
Conditions to Avoid	: Direct sunlight, extremely high or low temperatures, and incompatible materials.
Incompatible Materials	: Strong acids, strong bases, strong oxidizers. Water reactive materials.
Hazardous Decomposition Products	: None expected under normal conditions of use.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on Toxicological Effects - Product

Acute Toxicity (Oral)	: Not Classified.
Acute Toxicity (Dermal)	: Not Classified.
Acute Toxicity (Inhalation)	: Not Classified.
LD50 and LC50 Data	: Not Available
Skin Corrosion/Irritation	: Not Classified.
Eye Damage/Irritation	: Not Classified.
Respiratory or Skin Sensitization	: Not Classified.
Germ Cell Mutagenicity	: Not Classified.
Carcinogenicity	: Not Classified.
Specific Target Organ Toxicity (Repeated Exposure)	: Not Classified.
Reproductive Toxicity	: Not Classified.
Specific Target Organ Toxicity (Single Exposure)	: Not Classified.
Aspiration Hazard	: Not Classified.
Symptoms/Injuries After Inhalation	: Prolonged exposure may cause irritation.
Symptoms/Injuries After Skin Contact	: Prolonged exposure may cause skin irritation.
Symptoms/Injuries After Eye Contact	: May cause slight irritation to eyes.
Symptoms/Injuries After Ingestion	: Ingestion may cause adverse effects.
Chronic Symptoms	: None expected under normal conditions of use.

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### 11.2. Information on Toxicological Effects - Ingredient(s)

#### L-(-)-Norepinephrine (+)-bitartrate salt monohydrate (108341-18-0)

ATE US/CA (oral)	:	5.00 mg/kg body weight
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ATE US/CA (dermal)	:	5.00 mg/kg body weight
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#### Sodium Chloride (7647-14-5)

LD50 Oral Rat	:	3550 mg/kg (Species: Wistar)
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LD50 Dermal Rabbit	:	> 10000 mg/kg (Species: New Zealand White)
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LC50 Inhalation Rat	:	> 42 g/m <sup>3</sup> (Exposure time: 1 h)
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#### Sodium Metabisulfite (7681-57-4)

LD50 Oral Rat	:	1131 mg/kg
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LD50 Dermal Rat	:	> 2000 mg/kg
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#### Sodium Metabisulfite (7681-57-4)

IARC Group	:	3
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## SECTION 12: ECOLOGICAL INFORMATION

Aquatic Toxicity : Not determined for product.

Persistence/Biodegradability : Not determined for product.

Bioaccumulation : Not determined for product.

Mobility in Soil : Not determined for product.

## SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal Recommendations : Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Ecology - Waste Materials : Avoid release to the environment.

## SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

In Accordance with DOT	Not regulated for transport
In Accordance with IMDG	Not regulated for transport
In Accordance with IATA	Not regulated for transport
In Accordance with TDG	Not regulated for transport

## SECTION 15: REGULATORY INFORMATION

### 15.1. US Federal Regulations

#### **Sodium Chloride (7647-14-5)**

Listed on the United States TSCA (Toxic Substances Control Act) inventory

#### **Sodium Metabisulfite (7681-57-4)**

Listed on the United States TSCA (Toxic Substances Control Act) inventory

### 15.2. US State Regulations

#### **Sodium Metabisulfite (7681-57-4)**

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

U.S. - Massachusetts - Right To Know List

### 15.3. Canadian Regulations

#### **Sodium Chloride (7647-14-5)**

Listed on the Canadian DSL (Domestic Substances List)

#### **Sodium Metabisulfite (7681-57-4)**

Listed on the Canadian DSL (Domestic Substances List)

## SECTION 16: OTHER INFORMATION

### Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
DOT	US Department of Transportation Regulations
IATA	International Air Transport Association
LD50	Dosage producing 50% mortality
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
TWA	Time Weighted Average

### History:

**Issued Date** : 11.11.22  
**Revision Date** : Nil  
**Version** : 00

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

----End of SDS---