SAFETY DATA SHEET

for

Adrenalin® (epinephrine in sodium chloride injection), IV bag for intravenous use

1. Identification

Product Name:	Adrenalin® Injection
Synonyms:	Epinephrine Injection
CAS Number:	Mixture
Product Use:	Used as a prescription-only human therapeutic in the treatment of hypotension associated with septic shock.
Responsible Company:	Par Pharmaceutical (Endo)
Address:	1400 Atwater Drive Malvern, PA 19355
Manufacturer:	Galenica Senese S.r.l.,
Address:	Via Cassia Nord, 351, 53014 Monteroni D'arbia SI, Italy
General Information:	EVLLogisticsteam@endo.com www.endo.com
Emergency Contact:	+35312682000

General Use: This SDS is intended for people that could handle this product in an occupational setting such as but not limited to: Transporters, wholesalers, distributors, medical providers/staff and pharmacist/staff. This SDS is not intended for the patient or consumer of this product.

2. Hazards Identification

GHS Classification:

Health	Environmental	Physical
Not classified	Not classified	Not classified

GHS Label:

Symbols: None required Signal word: None required	
Hazard Statements	Precautionary Statements

3. Composition / Information on Ingredients

Component	C.A.S Number	Amount (%)
Epinephrine	51-43-4	0.0008-0.004
Disodium EDTA	6381-92-6	*
Sodium chloride	7647-14-5	*
Sodium hydroxide	1310-73-2	*q.s.* pH 4.0
Hydrochloric acid	7647-01-0	*q.s.* pH 4.0
L(+) – Tartaric acid	87-69-4	*
Water for Injection	7732-18-5	*

*Proprietary

4. First Aid Measures

Eye: Rinse with water. Get medical attention if irritation develops and persists.

Skin: Wash off with soap and water. Get medical attention if irritation develops and persists.

Inhalation: Move to fresh air. Call a physician if symptoms develop or persist.

Ingestion: Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.

5. Fire Fighting Measures

Suitable extinguishing media: Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media: Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical: During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters: Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions: Use water spray to cool unopened containers.

Specific methods: Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards: No unusual fire or explosion hazards noted.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures:
Keep unnecessary personnel away. Wear appropriate personal protective equipment (See Section 8).

Methods and materials for containment and cleaning up:
Wipe up with absorbent material. Following product recovery, flush area with water. Incineration of waste at an approved hazardous waste incinerator is recommended.

Environmental precautions:
Avoid discharge into drains, water courses or onto the ground.

7. Handling and Storage

General Handling
When handling, use appropriate personal protective equipment (see Section 8). Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and

procedural waste-water and waste disposal measures to prevent occupational exposure or environmental releases.

Storage
Store as directed by product packaging.

8. Exposure Controls / Personal Protection

Component Name	OSHA PEL (TWA)	ACGIH TLV (TWA)	Italy OEL (TWA)
Epinephrine	N.E.	N.E.	5 ppm 8 mg/m3

Engineering Controls:
In a manufacturing setting, local exhaust ventilation may be necessary to control air contaminants to their exposure limits. The use of local ventilation is recommended to control emissions near the source. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protective Equipment (PPE):

In a manufacturing setting, the following personal protective equipment requirements apply:

Eye Protection: Wear appropriate chemical safety goggles, safety glasses or face shield as described by OSHA's eye and face protection regulations in 29 CFR 1910.133. Have eyewash stations available where eye contact can occur.

Skin Protection: Wear gloves impervious to conditions of use. Additional protection may be necessary to prevent skin contact including the use of an apron, face shield, boots, or full body protection. A safety shower should be located in the work area.

Respiratory Protection: If exposure limits are exceeded, approved respiratory protection should be worn. Seek professional assistance for proper selection of respiratory protection.

9. Physical and Chemical Properties

Flash Point: Not available
Autoignition Temperature:
Not available

Lower Flammability Limit: Not available
Upper Flammability Limit:
Not available

Boiling Point: Not available
Melting Point: Not available
Vapor Pressure: Not available
Vapor Density: Not available
% Solubility in Water: Not available
Pour Point: Not available
Molecular Formula: Mixture
Odor/Appearance: Clear colorless solution

Specific Gravity: Not available
% Volatile: Not available
Evaporation Rate (Water=1): Not available
Viscosity: Not available
Octanol/Water Partition Coefficient: Not available
pH: Not available
Molecular Weight: Mixture

10. Stability and Reactivity

Reactivity: The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability: Material is stable under normal conditions.

Possibility of hazardous Reactions: No dangerous reaction known under conditions of normal use.

Conditions to avoid: Contact with incompatible materials.

Incompatible materials: Strong oxidizing agents.

Hazardous decomposition Products: No hazardous decomposition products are known.

11. Toxicology Information

Signs and Symptoms of Overexposure: Signs and symptoms of overexposure may include palpitation, pale complexion, sweating, nausea, vomiting, weakness, dizziness, headache, tremor, anxiety, apprehension, restlessness, and difficulty breathing.

Eye Contact: May cause eye irritation. Avoid contact with eyes.

Skin Contact: May be absorbed through the skin and mucous membranes and cause systemic effects. Avoid contact with skin.

Inhalation: Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Ingestion: Under normal conditions of intended use, this material is not expected to be an ingestion hazard.

Reproductive Effects: Under normal conditions of use, this material is not expected to have reproductive effects.

Chronic Effects: None of the components in this material are listed as a carcinogen by IARC, NTP or OSHA.

Genotoxic Effects: Under normal conditions of use, this material is not expected to have genotoxic effects.

Acute Toxicity Values:
LD_{50} (rat, oral) = 30 mg/kg (for Epinephrine base)
LD_{50} (rat, skin) = 62 mg/kg (for Epinephrine base) LD_{50}
(rat, oral) = 3,000 mg/kg (for Sodium chloride)

12. Ecological Information

The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

13. Disposal Considerations

Disposal instructions: Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

Local disposal regulations: Dispose in accordance with all applicable regulations.

Waste from residues / unused products: Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transportation Information

Based on available data this product has been determined non-hazardous according to USDOT/IATA criteria.

DOT
Not regulated as dangerous goods.

IATA
Not regulated as dangerous goods.

IMDG
Not regulated as dangerous goods.

15. Regulatory Information

U. S. Federal Regulations

Toxic Substance Control Act (TSCA): The following ingredients in this mixture are listed on the TSCA inventory: Epinephrine, Sodium chloride

Clean Water Act (CWA): There are no ingredients in this mixture listed in the CWA.

Clean Air Act (CAA): There are no ingredients in this mixture listed under the CAA.

Superfund Amendments and Reauthorization Act (SARA) Title III Information: There are no ingredients in this mixture listed under SARA.

California: This mixture contains no chemical(s) known to the State of California to cause cancer, birth defects or reproductive harm.

Canadian Environmental Protection Act: The following ingredients are listed on the Canadian Domestic Substances list (DSL): Epinephrine, Sodium chloride

European Inventory of Existing Chemicals (EINECS): The following ingredients are listed on the European Inventory of Existing Commercial Chemical Substances: Epinephrine, Sodium chloride

EU Classification: European labeling in accordance with EC directives.

16. Other Information

National Fire Protection Association (NFPA) Warnings

Health: 2	Flammability: 0	Reactivity: 0	Other: 0

Creation Date:	29 Jan 2024	**Revision Date:**	N/A

Disclaimer: **This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.**

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