

AAMA Medicine
Aug. 2008



MATERIAL SAFETY DATA SHEET

SECTION 1. Chemical Product and Company Identification

Product Name:— EPIPEN® & EPIPEN® JR

Common Name: (epinephrine) Auto-Injectors Preparation Date: August 1, 2002

Synonyms: Adrenalin Base

DISTRIBUTOR:

DEY, L.P.
2751 Napa Valley Corporate Drive
Napa, CA USA 94558

CONTACT INFORMATION:

Telephone: (707) 224-3200
Facsimile: (707) 224-1364

MANUFACTURER:

Meridian Medical Technologies, Inc
Columbia, MD 21046

SECTION 2. Composition/Information on Ingredients

Component	Substance Class	Chemical Formula	M.W.	Concentration (mg)	Chemical Abstract Society (CAS) #
Sodium chloride	Salt	NaCl	58.44	1.8	7647-14-5
Sodium metabisulfite	Sulfites/Sulfates	Na ₂ S ₂ O ₅	190.13	0.5	7681-57-4
(3,4-dihydroxyphenyl)- <i>a</i> -methylaminoethanol	Sympathomimetic catecholamine, vasoconstrictor	C ₉ H ₁₃ NO ₃	183.21	EPIPEN®: 0.3 EPIPEN® JR: 0.15	51-43-4

SECTION 3. Hazards Identification

Emergency Overview: This product has been approved for unit dosage identified on the package insert. Use only as directed by this information.

Large doses or accidental intravenous injection of epinephrine may result in cerebral hemorrhage due to sharp rise in blood pressure. Fatalities may also result from pulmonary edema because of peripheral vascular constriction together with cardiac stimulation. Do not inject into intravenously or into buttock.

Side effects of epinephrine may include palpitations, tachycardia, sweating, nausea and vomiting, respiratory difficulty, pallor, dizziness, weakness, tremor, headache, apprehension, nervousness and anxiety.



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SECTION 4. First Aid Measures

Eye contact: Flush affected eye(s) with large amounts of cool potable water for at least 15 minutes. Obtain medical attention.

Skin contact: Wash affected areas with soap and water after removing contaminated clothing. Obtain medical attention if contamination is significant and/or a skin reaction is evident.

Injection: Accidental injection into the hands or feet may result in loss of blood flow to the affected area and should be avoided. If there is an accidental injection into these areas, advise patient to go immediately to the nearest emergency room for treatment.

Inhalation: N/A.

Ingestion: If individual is conscious, rinse mouth with water. Never give anything by mouth to an unconscious person or to any individual having convulsions.

SECTION 5. Fire Fighting Measures

Flash Point (C): Not applicable.

Flammable Limits (LEL & UEL %): Not applicable.

Auto Ignition Temperature: Not applicable.

Extinguishing Media: Water spray, multipurpose dry chemical.

Fire Fighting Procedures: Wear full protective clothing and use self-contained breathing apparatus (SCBA) in the event of fire where bulk quantities are stored.

SECTION 6. Accidental Release Measures

Spill containment, treatment, and clean-up procedures:

Protective equipment may be necessary for spills. (Refer to Section 8, "Exposure Controls/Personal Protection" for guidance).

For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, collect spillage by sweeping up spilled material, and place in a labeled, sealed container for proper disposal.

SECTION 7. Handling and Storage

Avoid contact with eyes, skin, and clothing. Surfaces should be cleaned if contaminated with this substance.

Store in a dark place at room temperature (15°-30°C/59°-86°F). Do not refrigerate.

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SECTION 8. Exposure Controls/Personal Protection

- Engineering Controls:** No special ventilation requirements are needed for normal therapeutic dosage and administration.
- Respiratory Protection:** Not required for recommended dosage and administration. (See Section 5, "Fire Fighting Measures" for respiratory protection in the event of fire).
- Eye protection:** Not required for recommended dosage and administration. Workers should wear adequate eye protection to prevent eye contact.
- Skin protection:** Adequate protective clothing and gloves should be worn when routine handling or spill cleanup may result in skin contact. Wash hands thoroughly after handling this material.
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SECTION 9. Physical and Chemical Properties

Physical and chemical properties of product determined as a whole.

- Appearance and Odor:** Clear, colorless and odorless solution.
- pH:** 2.2-5.0
- Specific Gravity (H₂O = 1):** ≈1
- Boiling Point (C):** ≈100° C
- Melting Point (C):** N/A
- Vapor Pressure:** N/D
- Evaporation Rate:** N/D
- Solubility in Water:** Complete
- N/A = Not applicable. N/D = Not determined.
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SECTION 10. Stability and Reactivity

- Stability:** Stable.
- Incompatibility:** Not determined.
- Hazardous Decomposition:** Not determined.
- Conditions to avoid:** Contact with strong acids, bases, or oxidizers.



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SECTION 11. Toxicological Information

Epinephrine: RTECS #: DO2625000
ORL-MUS LD50 50 mg/kg
SCU-RAT LD50 5 mg/kg
IVN-RAT LD50 0.15 mg/kg
IPR-MUS LD50 4 mg/kg
SCU-RBT LD50 4 mg/kg

Sodium Chloride: ORL-RAT LD50: 3000 mg/kg
IHL-RAT LC50: > 42 gm/m³ /1H

Sodium metabisulfite: Human LD=10G/75KG; TLV=5MG/M3

Refer to the Registry of Toxic Effects of Chemical Substances (RTECS) for definition of abbreviations used in the above text and for additional information.

Other component toxicological information:

Pharmacological Activity:

Epinephrine is a sympathomimetic drug, acting on both alpha and beta receptors. It is the drug of choice for the emergency treatment of severe allergic reactions (Type I) to insect stings or bites, foods, drugs, and other allergens. It can also be used in the treatment of idiopathic or exercise-induced anaphylaxis. Epinephrine when given subcutaneously or intramuscularly has a rapid onset and short duration of action. The strong vasoconstrictor action of epinephrine through its effect on alpha adrenergic receptors acts quickly to counter vasodilation and increased vascular permeability which can lead to loss of intravascular fluid volume and hypotension during anaphylactic reactions. Epinephrine through its action on beta receptors on bronchial smooth muscle causes bronchial smooth muscle relaxation which alleviates wheezing and dyspnea. Epinephrine also alleviates pruritis, urticaria, and angioedema and may be effective in relieving gastrointestinal and genitourinary symptoms associated with anaphylaxis.

Dose Toxicity:

Overdosage or inadvertent intravascular injection of epinephrine may cause cerebral hemorrhage resulting from a sharp rise in blood pressure. Fatalities may also result from pulmonary edema because of peripheral vascular constriction together with cardiac stimulation.

Reproductive Effects:

Studies of epinephrine in animals to evaluate the effects on fertility have not been conducted.

Pregnancy:

Teratogenic Effects: Pregnancy Category C:

Epinephrine has been shown to be teratogenic in rats when given in doses about 25 times the human dose. There are no adequate and well-controlled studies in pregnant women.

Genotoxicity:

Studies of epinephrine in animals to evaluate the mutagenic potential have not been conducted.

Carcinogenicity:

Studies of epinephrine in animals to evaluate the carcinogenic potential have not been conducted.



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For further product specific information, including precautions, adverse reactions, and dosage, refer to package insert.

SECTION 12. Ecological Information

Data not yet available.

SECTION 13. Disposal Considerations

Dispose of material in accordance with local, state, and federal regulations.

SECTION 14. Transport Information

DOT Proper Shipping Name and Identification Number: Not regulated.

Hazard class: Not applicable.

SECTION 15. Regulatory Information

None.

SECTION 16. Other Information

The information provided herein represents the most reasonable current information available when this assessment was performed. It is believed to be accurate and dependable. DEY, L.P. makes no representation as to the accuracy or sufficiency of this information. Use only as directed by the package insert. DEY, L.P. will assume no liability for the improper use of this product.

Preparation date: August 1, 2002