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Mylan®

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EPIPEN® AND EPIPEN® JR

SAFETY DATA SHEET

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

Product Identifier

Product Name: EpiPen® and EpiPen® Jr

Synonyms: Epinephrine Auto-Injector

Intended Use Of The Product

Pharmaceutical. For emergency treatment of severe allergic reaction or anaphylaxis. Use only as directed. Refer to product insert for usage instructions and product information.

Name, Address, And Telephone Of The Responsible Party

Supplier:
Mylan Specialty L.P.
110 Allen Road
Basking Ridge, NJ 07920, USA
http://www.mylanspecialty.com/
+1 877-446-3679

Manufacturer:
Meridian Medical Technologies,
a Pfizer company
Columbia, MD 21046 U.S.A

Emergency Telephone Number

Emergency Number : 877-446-3679

2. HAZARDS IDENTIFICATION

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

Classification Of The Substance Or Mixture

Classification (GHS-US)
Not classified

Label Elements

GHS-US Labeling Not applicable

Other Hazards Not available

Unknown Acute Toxicity (GHS US) Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Name	Product Identifier	%	Classification (GHS-US)
Water	(CAS No.) 7732-18-5	99.13 - 99.18	Not classified
Sodium chloride	(CAS No.) 7647-14-5	0.6	Eye Irrit. 2A, H319
Sodium metabisulfite	(CAS No.) 7681-57-4	0.167	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318 Resp. Sens. 1B, H334 Skin Sens. 1B, H317
Epinephrine	(CAS No.) 51-43-4	0.05 - 0.1	Acute Tox. 2 (Dermal), H310 Muta. 2, H341

Full text of H-phrases: see section 16

4. FIRST AID MEASURES

Description Of First Aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show label if possible).

Inhalation: The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

Skin Contact: Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

Eye Contact: The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention.

Most Important Symptoms And Effects Both Acute and Delayed

General: Effects reported during consumer use include palpitations, tachycardia, sweating, nausea, vomiting, respiratory difficulty, pallor, dizziness, weakness, tremor, headache, apprehension, nervousness and anxiety.

Inhalation: Inhalation of vapor and/or mist may cause respiratory irritation and sensitization.

Skin Contact: May cause skin irritation and sensitization. This product contains sodium metabisulfite, a sulfite that may cause allergic-type reactions.

Eye Contact: May cause eye irritation.

Ingestion: May cause nausea, vomiting and diarrhea.

Injection: Epinephrine is a strong vasoconstrictor; therefore accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area. Large doses or accidental intravenous injection may result in cerebral hemorrhage due to sharp rise in blood pressure. This product contains sodium metabisulfite, a sulfite that may cause allergic-type reactions.

Indication Of Any Immediate Medical Attention And Special Treatment Needed

If exposed or concerned, get medical advice and attention. In the event of accidental injection, go immediately to the nearest emergency room.

5. FIREFIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: Do not use a heavy water stream.

Special 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.

Advice For Firefighters

Firefighting Instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Do not allow run-off from fire fighting to enter drains or water courses.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Not available

Other Information: Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment And Emergency Procedures

General Measures: Avoid all eye and skin contact and do not breathe vapor and mist.

For Non-Emergency Personnel

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

Emergency Procedures: Evacuate unnecessary personnel.

For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Environmental Precautions

Prevent entry to sewers and public waters.

Methods And Material For Containment And Cleaning Up

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

Reference To Other Sections

See Heading 8, Exposure Controls and Personal Protection.

7. HANDLING AND STORAGE

Precautions For Safe Handling

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

Hygiene Measures: This SDS is for a pharmaceutical agent – Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

Conditions For Safe Storage, Including Any Incompatibilities

Storage Conditions: Keep container closed when not in use. Keep away from heat and direct sunlight. Do not refrigerate.

Storage Temperature: 20-25°C (68-77°F)

Special Rules on Packaging: Examine clear window of autoinjector unit periodically. Solution should be clear. If the solution is discolored or contains solid particles (precipitate), replace the unit.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

Sodium metabisulfite (7681-57-4)		
USA ACGIH	ACGIH TWA (mg/m³)	5 mg/m³
USA NIOSH	NIOSH REL (TWA) (mg/m3)	5 mg/m³
Québec	VEMP (mg/m³)	5 mg/m³

Exposure Controls

Appropriate Engineering Controls: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal Protective Equipment: Not generally required when using this product. The use of personal protective equipment may be necessary as conditions warrant.

Hand Protection: Not required for normal conditions of use

Eye Protection: In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

Skin and Body Protection: In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

Respiratory Protection: When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information On Basic Physical And Chemical Properties

Physical state	:	Liquid
Appearance	:	Clear, Colorless
Odor	:	Odorless
Odor threshold	:	Not available
pH	:	2.2 - 5
Relative evaporation rate (butyl acetate=1)	:	Not available
Melting point	:	Not available
Freezing point	:	Not available
Boiling point	:	≈ 100°C (212°F)
Flash point	:	Not available
Auto-ignition temperature	:	Not available

Decomposition temperature	:	Not available
Flammability (solid, gas)	:	Not available
Lower flammable limit	:	Not available
Upper flammable limit	:	Not available
Vapor pressure	:	Not available
Relative vapor density at 20 °C	:	Not available
Relative density	:	≈ 1 (water=1)
Specific gravity density	:	Not available
Solubility	:	Soluble in water.
Log Pow	:	Not available
Log Kow	:	Not available
Viscosity, kinematic	:	Not available
Viscosity, dynamic	:	Not available
Explosion data - sensitivity to mechanical impact	:	Not available
Explosion data - sensitivity to static discharge	:	Not available

10. STABILITY AND REACTIVITY

Reactivity Hazardous reactions will not occur under normal conditions.

Chemical Stability Stable under normal conditions.

Possibility Of Hazardous Reactions Hazardous polymerization will not occur.

Conditions To Avoid Direct sunlight. Extremely high or low temperatures. Epinephrine deteriorates rapidly on exposure to air or light.

Incompatible Materials Strong acids. Strong bases.

11. TOXICOLOGICAL INFORMATION

Information On Toxicological Effects - Product

Acute Toxicity Not classified

LD50 and LC50 Data Not available

Skin corrosion/irritation: Not classified (pH: 2.2 – 5)

Serious eye damage/irritation: Not classified (pH: 2.2 – 5)

Respiratory or skin sensitization: Not classified

Germ cell mutagenicity:Not classified

Teratogenicity: Not classified

Carcinogenicity: Not classified

Reproductive toxicity: Not classified

Specific target organ toxicity (single exposure): Not classified

Specific target organ toxicity (repeated exposure): Not classified

Information On Toxicological Effects - Ingredient(s)

LD50 and LC50 Data

Sodium chloride (7647-14-5)	
LD50 oral rat	3 g/kg
LD50 dermal rabbit	> 10 g/kg
LC50 inhalation rat (mg/l)	> 42 g/m³ (Exposure time: 1 h)
ATE (oral)	3000 mg/kg

Sodium metabisulfite (7681-57-4)	
LD50 oral rat	1131 mg/kg
LD50 dermal rat	> 2 g/kg
ATE (oral)	1131 mg/kg

Epinephrine (51-43-4)	
LD50 dermal rat	62 mg/kg
ATE (dermal)	62 mg/kg

Sodium metabisulfite (7681-57-4)	
IARC group	3

12. ECOLOGICAL INFORMATION

Toxicity

Sodium chloride (7647-14-5)	
LC50 fish 1	5560 - 6080 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 Daphnia 1	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 2	340.7 - 469.2 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

Sodium metabisulfite (7681-57-4)	
LC50 fish 1	32 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 1	89 mg/l (Exposure time: 24 h - Species: Daphnia magna Straus)
EC50 other aquatic organisms 1	48 mg/l (Exposure time: 72 h - Species: Desmodesmus subspicatus)
EC50 other aquatic organisms 2	40 mg/l (Exposure time: 96 h - Species: Desmodesmus subspicatus)

Persistence And Degradability

EpiPen® and EpiPen® Jr	
Persistence and degradability	Not established.

Bioaccumulative Potential

EpiPen® and EpiPen® Jr	
Bioaccumulative potential	Not established.

Sodium chloride (7647-14-5)	
BCF fish 1	(no bioaccumulation)

Sodium metabisulfite (7681-57-4)	
Log Pow	-3.7 (at 25 °C)

13. DISPOSAL CONSIDERATIONS

Sewage Disposal Recommendations: Do not empty into drains.

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations.

Additional Information: Contaminated sharps should be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a Safe Syringe Disposal Program.

14. TRANSPORT INFORMATION

In accordance with ICAO/IATA/DOT/TDG

UN Number Not available

UN Proper Shipping Name Not available

15. REGULATORY INFORMATION

US Federal regulations

Water (7732-18-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

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

Epinephrine (51-43-4)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

US State regulations

Sodium chloride (7647-14-5)
U.S. - Texas - Effects Screening Levels - Long Term
U.S. - Texas - Effects Screening Levels - Short Term

Sodium metabisulfite (7681-57-4)
U.S. - Connecticut - Hazardous Air Pollutants - HLVs (30 min)
U.S. - Connecticut - Hazardous Air Pollutants - HLVs (8 hr)
U.S. - Hawaii - Occupational Exposure Limits - TWAs
U.S. - Idaho - Non-Carcinogenic Toxic Air Pollutants - Acceptable Ambient Concentrations
U.S. - Idaho - Non-Carcinogenic Toxic Air Pollutants - Emission Levels (ELs)
U.S. - Massachusetts - Right To Know List
U.S. - Michigan - Occupational Exposure Limits - TWAs
U.S. - Minnesota - Hazardous Substance List
U.S. - Minnesota - Permissible Exposure Limits - TWAs
U.S. - New Hampshire - Regulated Toxic Air Pollutants - Ambient Air Levels (AALs) - 24-Hour
U.S. - New Hampshire - Regulated Toxic Air Pollutants - Ambient Air Levels (AALs) - Annual
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - New Jersey - Special Health Hazards Substances List
U.S. - North Dakota - Air Pollutants - Guideline Concentrations - 8-Hour
U.S. - Pennsylvania - RTK (Right to Know) List
U.S. - Tennessee - Occupational Exposure Limits - TWAs
U.S. - Texas - Effects Screening Levels - Long Term
U.S. - Texas - Effects Screening Levels - Short Term
U.S. - Vermont - Permissible Exposure Limits - TWAs
U.S. - Washington - Permissible Exposure Limits - STELs
U.S. - Washington - Permissible Exposure Limits - TWAs
U.S. - Wisconsin - Hazardous Air Contaminants - All Sources - Emissions From Stack Heights 25 Feet to Less Than 40 Feet
U.S. - Wisconsin - Hazardous Air Contaminants - All Sources - Emissions From Stack Heights 40 Feet to Less Than 75 Feet
U.S. - Wisconsin - Hazardous Air Contaminants - All Sources - Emissions From Stack Heights 75 Feet or Greater
U.S. - Wisconsin - Hazardous Air Contaminants - All Sources - Emissions From Stack Heights Less Than 25 Feet

Epinephrine (51-43-4)
U.S. - Colorado - Hazardous Wastes - Discarded Chemical Products, Off-Specification Species, Container and Spill Residues
U.S. - Delaware - Pollutant Discharge Requirements - Reportable Quantities
U.S. - Louisiana - Reportable Quantity List for Pollutants
U.S. - Massachusetts - Oil & Hazardous Material List - Groundwater Reportable Concentration - Reporting Category 1
U.S. - Massachusetts - Oil & Hazardous Material List - Groundwater Reportable Concentration - Reporting Category 2
U.S. - Massachusetts - Oil & Hazardous Material List - Reportable Quantity
U.S. - Massachusetts - Oil & Hazardous Material List - Soil Reportable Concentration - Reporting Category 1
U.S. - Massachusetts - Oil & Hazardous Material List - Soil Reportable Concentration - Reporting Category 2
U.S. - Massachusetts - Right To Know List
U.S. - Massachusetts - Toxics Use Reduction Act
U.S. - Michigan - Polluting Materials List
U.S. - Nebraska - "P" Listed Hazardous Wastes
U.S. - New Jersey - Discharge Prevention - List of Hazardous Substances
U.S. - New York - Reporting of Releases Part 597 - List of Hazardous Substances
U.S. - North Dakota - Hazardous Wastes - Discarded Chemical Products, Off-Specification Species, Container and Spill Residues
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List
U.S. - Pennsylvania - RTK (Right to Know) List
U.S. - Texas - Effects Screening Levels - Long Term
U.S. - Texas - Effects Screening Levels - Short Term
U.S. - Vermont - Hazardous Waste - Acutely Hazardous Wastes
U.S. - Vermont - Hazardous Waste - Hazardous Constituents
U.S. - Washington - Dangerous Waste - Discarded Chemical Products List

Canadian regulations

Water (7732-18-5)	
Listed on the Canadian DSL (Domestic Substances List) inventory.	
WHMIS Classification	Uncontrolled product according to WHMIS classification criteria

Sodium chloride (7647-14-5)	
Listed on the Canadian DSL (Domestic Substances List) inventory.	
WHMIS Classification	Uncontrolled product according to WHMIS classification criteria

Sodium metabisulfite (7681-57-4)
Listed on the Canadian DSL (Domestic Substances List) inventory.

WHMIS Classification	Uncontrolled product according to WHMIS classification criteria

Epinephrine (51-43-4)
Listed on the Canadian DSL (Domestic Substances List) inventory.

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by CPR.

16. OTHER INFORMATION

Indication of Changes : Revision date 2/25/2013

Data Sources : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

Other Information : This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

GHS Full Text Phrases:

Acute Tox. 2 (Dermal)	Acute toxicity (dermal) Category 2
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Muta. 2	Germ cell mutagenicity Category 2
Resp. Sens. 1B	Respiratory sensitisation Category 1B
Skin Sens. 1B	Skin sensitization Category 1B
H302	Harmful if swallowed
H310	Fatal in contact with skin
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H319	Causes serious eye irritation
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H341	Suspected of causing genetic defects

Party responsible for the preparation of this document:

Mylan Global Environmental, Health, and Safety Department

Phone Number: 304-599-2595

This MSDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions.

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.