EPIPEN® AND EPIPEN® JR

SAFETY DATA SHEET

In accordance with The Model Work Health and Safety Regulations, and the Globally Harmonized System of Classification and Labelling of Chemicals 3rd Revised Edition.

1. IDENTIFICATION: PRODUCT IDENTIFIER & CHEMICAL IDENTITY

1.1 Product Identifier

Product Form: Mixture
Product Name: EpiPen® and EpiPen® Jr
Synonyms: Epinephrine Auto-Injector
SUSMP Name: Adrenaline

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

1.2.1 Relevant Identified Uses

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

1.2.2 Uses Advised Against: Intravenous administration

1.3 Details of the Supplier of the Safety Data Sheet

Supplier:
Alphapharm Pty Ltd
(A Mylan Company)
Level 1, 30 The Bond
30-34 Hickson Road,
Millers Point, NSW |Australia
Phone: (02) 9298 3999
www.alphapharm.com.au

1.4 Emergency Telephone Number

Emergency Number : (02) 9298 3999

2. HAZARD(S) 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.

2.1 Classification Of The Substance Or Mixture

Classification GHS-AU Not classified

2.2 Label Elements

GHS-AU Labelling No labelling applicable

2.3 Non-GHS Hazards Not available

2.4 Other Hazards Not available

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.1 Substance Not applicable

3.2 Mixture

Name	Product Identifier	%	GHS-AU Classification
Water	(CAS No.) 7732-18-5	99.13 - 99.18	Not classified
Sodium chloride	(CAS No.) 7647-14-5	0.6	Not classified
Sodium metabisulfite	(CAS No.) 7681-57-4	0.167	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318
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

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 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.

4.2 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.

4.3 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. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.
Unsuitable Extinguishing Media: Do not use a heavy water stream.

5.2 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.

5.3 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: None
Hazchem Code: None

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment And Emergency Procedures

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

6.1.1 For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).
Emergency Procedures: Evacuate unnecessary personnel.

6.1.2 For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

6.2 Environmental Precautions

Prevent entry to sewers and public waters.

6.3 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.

6.4 Reference To Other Sections

See Heading 8, Exposure Controls and Personal Protection.

7. HANDLING AND STORAGE, INCLUDING HOW THE CHEMICAL MAY BE SAFELY USED

7.1 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.

7.2 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.

7.3. Specific End Use(s)

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

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

8.1 Control Parameters

Sodium metabisulfite (7681-57-4)		
USA ACGIH	ACGIH TWA (mg/m³)	5 mg/m³
Australia	Australia TWA (mg/m³)	5 mg/m³

8.2 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. An approved respirator for protection should be used if respirators are found to be necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information On Basic Physical And Chemical Properties

Physical state	:	Liquid
Appearance	:	Clear, Colourless
Odor	:	Odourless
Odor threshold	:	Not available
pH	:	2.2-5
Relative evaporation rate (butyl acetate=1)	:	Not available
Melting point / 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
Upper and Lower flammable limits	:	Not available
Vapor pressure	:	Not available
Relative vapor density at 20 °C	:	Not available
Relative density	:	≈ 1 (water=1)
Solubility	:	Soluble in water.
Partition coefficient: n-octanol/water	:	Not available
Viscosity	:	Not available

9.2. Other information No additional information available

10. STABILITY AND REACTIVITY

10.1 Reactivity Hazardous reactions will not occur under normal conditions.
10.2 Chemical Stability Stable under normal conditions.
10.3 Possibility Of Hazardous Reactions Hazardous polymerization will not occur.

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

10.5 Incompatible Materials Strong acids. Strong bases.

10.6 Hazardous Decomposition Products Nitrogen oxides. Carbon oxides (CO, CO_2)

11. TOXICOLOGICAL INFORMATION

11.1 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 mutagenicitn: 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
Aspiration hazard: Not classified

Symptoms/Injuries General: Effects reported during consumer use include palpitations, tachycardia, sweating, nausea, vomiting, respiratory difficulty, pallor, dizziness, weakness, tremor, headache, apprehension, nervousness and anxiety.
Symptoms/Injuries After Inhalation: Inhalation of vapor and/or mist may cause respiratory irritation and sensitization.
Symptoms/Injuries After Skin Contact: May cause skin irritation and sensitization. This product contains sodium metabisulfite, a sulfite that may cause allergic-type reactions.
Symptoms/Injuries After Eye Contact: May cause eye irritation.
Symptoms/Injuries After Ingestion: May cause nausea, vomiting and diarrhea.
Symptoms/Injuries After 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.

11.2 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)
Sodium metabisulfite (7681-57-4)	
LD50 oral rat	1131 mg/kg
LD50 dermal rat	> 2 g/kg
Epinephrine (51-43-4)	
LD50 dermal rat	62 mg/kg
Sodium metabisulfite (7681-57-4)	
IARC group	3

12. ECOLOGICAL INFORMATION

12.1 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)

12.2 Persistence And Degradability

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

12.3 Bioaccumulative Potential

EpiPen® and EpiPen® Jr	
Bioaccumulative potential	Not expected to bioaccumulate

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

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

12.4 Mobility in Soil No additional information available

12.5 Results of PBT and vPvB assessment No additional information available

12.6 Other Adverse Effects No additional information available

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 handled with care and 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 syringe disposal program.

14. TRANSPORT INFORMATION

According to UNRTDG and ADG Code Not regulated for transport

15. REGULATORY INFORMATION

15.1 National Regulations

Sodium chloride (7647-14-5)

Listed on AICS (Australian Inventory of Chemical Substances)
Listed on the Canadian DSL (Domestic Sustances List)
Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)
Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory
Listed on the Korean ECL (Existing Chemicals List)
Listed on NZIoC (New Zealand Inventory of Chemicals)
Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

Water (7732-18-5)

Listed on AICS (Australian Inventory of Chemical Substances)
Listed on the Canadian DSL (Domestic Sustances List)
Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)
Listed on the Korean ECL (Existing Chemicals List)
Listed on NZIoC (New Zealand Inventory of Chemicals)
Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

Sodium metabisulfite (7681-57-4)

Listed on AICS (Australian Inventory of Chemical Substances)
Listed on the Canadian DSL (Domestic Sustances List)
Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)
Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory
Listed on the Korean ECL (Existing Chemicals List)
Listed on NZIoC (New Zealand Inventory of Chemicals)
Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)
Listed on the United States TSCA (Toxic Substances Control Act) inventory
Listed on the Canadian IDL (Ingredient Disclosure List)

Epinephrine (51-43-4)

Listed on AICS (Australian Inventory of Chemical Substances)
Listed on the Canadian DSL (Domestic Sustances List)
Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)
Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory
Listed on NZIoC (New Zealand Inventory of Chemicals)
Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)

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

15.2 International Agreements

No additional information available

15.3 Australia National Regulations

Sodium chloride (7647-14-5)	
High Volume Industrial Chemicals List	Present

Water (7732-18-5)	
High Volume Industrial Chemicals List	Present

Sodium metabisulfite (7681-57-4)	
Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)	Appendix E – A, G3 Appendix F - Safety Statements – 1,4 (>50%) Appendix F - Warning Statements – 5, 26 (>50%) Schedule 5 – When packed for domestic use except in preparations containing <=10% Sodium metabisulphite
High Volume Industrial Chemicals List	Present

Epinephrine (51-43-4)	
Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 3 - <=1% (for preparations except in preparations containing <=0.02% of Adrenaline unless packed and labelled for injection) Schedule 4 – Except when included in Schedule 3, or in preparations containing <=0.02% of Adrenaline unless packed and labelled for injection.

15.4 Australia Territorial Regulations

No additional information available

16. ANY OTHER RELEVANT INFORMATION

Indication of Changes : 01/08/2014

Regulatory Reference : In accordance with The Model Work Health and Safety Regulations, and the Globally Harmonized System of Classification and Labelling of Chemicals 3rd Revised Edition.

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.

Full text of H-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
Muta. 2	Germ cell mutagenicity Category 2
H302	Harmful if swallowed
H310	Fatal in contact with skin
H318	Causes serious eye damage
H341	Suspected of causing genetic defects

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.

SDS AU (The Model Work Health and Safety Regulations)