# Epinephrine (EpiPen® and EpiPen Jr®) Auto-Injector

SAFETY DATA SHEET

North America GHS

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations & the Hazardous Products Regulation (February 11, 2015) & NORMA Oficial Mexicana NOM-018-STPS-2015

## 1. IDENTIFICATION

### Product identifier

**Product Name:** Epinephrine (EpiPen® and EpiPen Jr®) Auto-Injector

**Synonyms:** EpiPen ® (epinephrine injection, USP) Auto-Injector 0.3 mg; EpiPen Jr® (epinephrine injection, USP) Auto-Injector 0.15 mg;

### Other means of identification

**Other Information:** No other information

### Recommended use of the chemical and restrictions on use

**Recommended Use:** Pharmaceutical. Use only as directed.

The intent of this safety data sheet (SDS) is to provide safety information for occupational handling of this product. This information may not be relevant for medical use of this product. Patients/ consumers should consult the package insert/ product label/ physician/ pharmacist for information regarding the usage of this product. For information on the ingredients used in this product, refer to the appropriate SDS for each ingredient.

**Uses advised against:** No information available.

### Details of the supplier of the safety data sheet

Mylan Inc.
Robert J. Coury Global Center
1000 Mylan Blvd.
Canonsburg, PA 15317, USA
+1.724.514.1800

**Contact e-mail:** SDScontact@viatris.com

### Emergency telephone number

**Emergency Telephone:** 24 hr. Emergency Contact ChemTel
**International:** +1-813-248-0585
**US & Canada:** 1-800-255-3924
**Mexico:** 800-099-0731

### Other Contact Information

**FDA Adverse Events Reporting Number:** For reporting adverse health events call: +1 877-446-3679

## 2. HAZARDS IDENTIFICATION

***Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk***

### Classification

Not classified

### Label elements

Not classified

### Other Hazards

No information available.

### Unknown acute toxicity

No information available

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Mixture**

| Chemical name | CAS No | Weight-% | Hazard statements |
|---|---|---|---|
| Epinephrine bitartrate | 51-42-3 | 0.05 - 0.1 | H300 - Fatal if swallowed<br>H319 - Causes serious eye irritation<br>H361 - Suspected of damaging fertility or the unborn child<br>H370 - Causes damage to organs |

## 4. FIRST AID MEASURES

*This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.*

### Description of first aid measures

**Overdose:** Refer to information on package labeling and packaging. In case of overdose, get medical help or contact a Poison Control Center right away.

**General advice:** Never give anything by mouth to an unconscious person. IF exposed or concerned: Get medical advice/attention. Show this safety data sheet to the doctor in attendance.

**Inhalation:** IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention immediately if symptoms occur.

**Skin contact:** Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention.

**Eye contact:** In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

**Ingestion:** Do not induce vomiting without medical advice. Rinse mouth thoroughly with water. Get medical attention if symptoms occur.

**Self-protection of the first aider:** First aider: Pay attention to self-protection. Do not breathe dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

### Most important symptoms and effects, both acute and delayed

**Symptoms:** Headache. Anxiety. Increased Blood pressure. Cardiac arrhythmias.

### Indication of any immediate medical attention and special treatment needed

Treat symptomatically. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

## 5. FIRE-FIGHTING MEASURES

### Extinguishing media

**Suitable Extinguishing Media:** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Unsuitable extinguishing media:** None known.

### Specific hazards arising from the chemical

**Fire hazard:** Not flammable.

**Explosive hazard:** Not an explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

**Hazardous combustion products:** Carbon oxides. Nitrogen oxides.

### Advice for firefighters

**Precautionary measures in case of fire:** Standard procedure for chemical fires.

**Firefighting instructions:** Use water spray or fog; do not use straight streams.

**Protection of Firefighters:** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

**Other Information:** Refer to Section 9 for flammability properties.

## 6. ACCIDENTAL RELEASE MEASURES

*This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.*

### Personal precautions, protective equipment and emergency procedures

**Personal precautions:** Avoid contact with skin, eyes or clothing. Do not breathe dust/fume/gas/mist/vapors/spray. Use personal protective equipment as required.

### For non-emergency personnel

**Personal Protective Equipment:** Use personal protective equipment as required.

**Emergency procedures:** Evacuate personnel to safe areas.

### For emergency responders

**Personal Protective Equipment:** Use personal protective equipment as required.

**Emergency procedures:** Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources if safe to do so.

### Environmental precautions

Do not flush into surface water or sanitary sewer system. Should not be released into the environment. See Section 12 for additional Ecological Information.

### Methods and material for containment and cleaning up

**Methods for containment:** Prevent further leakage or spillage if safe to do so.
**Methods for cleaning up:** Use appropriate personal protective equipment (PPE). Carefully shovel or sweep up spilled material and place in suitable container. Avoid generating dust. For spills:. Soak up with inert absorbent material. Use clean non-sparking tools to collect absorbed material. Avoid breathing dust or spray mist.
**Prevention of secondary hazards:** Clean contaminated objects and areas thoroughly observing environmental regulations.

### Reference to other sections

See section 8 for more information. See section 13 for more information.

## 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.

### Conditions for safe storage, including any incompatibilities

**Storage Conditions:** Keep at temperatures between 20 and 25 °C (68 and 77 °F). Do not refrigerate. Protect from light. Keep out of reach of children.
**Specific end use(s):** Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

*This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.*

### Control parameters

**Exposure Limits:** No information available

### Exposure controls

**Appropriate engineering controls:** 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.

### Individual protection measures, such as personal protective equipment

**Hand protection:** Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.
**Eye/face protection:** Safety glasses with side shields are recommended for medical or industrial exposures.
**Skin and body protection:** Wear suitable protective clothing.
**Respiratory protection:** Use appropriate respiratory protection.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

| | |
|---|---|
| **Physical state:** | Liquid |
| **Appearance:** | clear |
| **Color:** | colorless |
| **Odor:** | Odorless |
| **Odor threshold:** | No data available |
| **pH:** | 2.2-5 |
| **Melting point / freezing point:** | No data available |
| **Boiling point / boiling range:** | ≈ 100 °C (212 °F) °C / °F |
| **Flash point:** | No data available |
| **Evaporation rate:** | No data available |
| **Flammability (solid, gas):** | No data available |
| **Upper flammability limit:** | No data available |
| **Lower flammability limit:** | No data available |
| **Vapor pressure:** | No data available |
| **Vapor density:** | No data available |
| **Relative density:** | ≈ 1 (water = 1) |
| **Water solubility:** | Soluble in water |
| **Solubility in other solvents:** | No data available |
| **Partition coefficient:** | No data available |
| **Autoignition temperature:** | No data available |
| **Decomposition temperature:** | No data available |
| **Kinematic viscosity:** | No data available |
| **Dynamic viscosity:** | No data available |
| **Explosive properties:** | No data available |
| **Oxidizing properties:** | No data available |

### Other Information

**VOC Content (%):** No data available

## 10. STABILITY AND REACTIVITY

**Reactivity**
Hazardous reactions will not occur under normal conditions.
**Chemical stability**
Stable under normal conditions.
**Possibility of hazardous reactions**
None under normal processing.
**Conditions to avoid**
Extremes of temperature and direct sunlight.
**Incompatible materials**
Strong oxidizing agents, strong acids, and strong bases.
**Hazardous decomposition products**
Decomposition will not occur under normal conditions.

## 11. TOXICOLOGICAL INFORMATION

**Information on toxicological effects**
**Information on likely routes of exposure**
**Inhalation:** Specific test data for the substance or mixture is not available.
**Ingestion:** Based on available data, the classification criteria are not met.
**Eye contact:** Specific test data for the substance or mixture is not available.
**Skin contact:** Specific test data for the substance or mixture is not available.
**Symptoms related to the physical, chemical and toxicological characteristics**
**Symptoms:** Headache. Anxiety. Increased Blood pressure. Cardiac arrhythmias.
**Delayed and immediate effects as well as chronic effects from short and long-term exposure**
**Skin corrosion/irritation:** Based on available data, the classification criteria are not met.
**Serious eye damage/eye irritation:** Based on available data, the classification criteria are not met.
**Respiratory or skin sensitization:** Based on available data, the classification criteria are not met.
**Germ cell mutagenicity:** Based on available data, the classification criteria are not met.
**Carcinogenicity:** Based on available data, the classification criteria are not met.
**Reproductive toxicity:** Based on available data, the classification criteria are not met.
**STOT - single exposure:** Based on available data, the classification criteria are not met.
**STOT - repeated exposure:** Based on available data, the classification criteria are not met.
**Aspiration hazard:** Based on available data, the classification criteria are not met.
**Numerical measures of toxicity**
**Acute toxicity:** No information available

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity**
No information available.
**Persistence and degradability**
No information available.
**Bioaccumulation**
No information available.
**Mobility**
No information available.
**Other adverse effects**
No information available.

## 13. DISPOSAL CONSIDERATIONS

**Waste treatment methods**
Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable. Dispose of waste in accordance with environmental legislation. Do not flush into surface water or sanitary sewer system.

## 14. TRANSPORT INFORMATION

*Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.*

| | |
|---|---|
| **DOT** | Not regulated |
| **TDG** | Not regulated |
| **IATA** | Not regulated |

**IMDG** Not regulated

## 15. REGULATORY INFORMATION

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

**International Regulations**

**Ozone-depleting substances (ODS):** Not applicable
**Persistent Organic Pollutants:** Not applicable
**The Rotterdam Convention:** Not applicable

**US Federal Regulations**

**SARA 313:** Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

**CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

**CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

**U.S. State Right-to-Know Regulations**

**US State Regulations:**

| Chemical name | New Jersey | Massachusetts | Pennsylvania |
|---|---|---|---|
| Sodium metabisulfite<br>7681-57-4 | X | X | X |

**Canada**

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

## 16. OTHER INFORMATION

**Revision Date:** 13-August-2025

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

**Key or legend to abbreviations and acronyms used in the safety data sheet:**

**Legend, Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA: TWA (time-weighted average)
STEL: STEL (Short Term Exposure Limit)

**Party responsible for the preparation of this document:**

Viatris Global Environmental, Health, and Safety Department - Occupational Toxicology
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*This SDS 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.*

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