

**SECTION 1: IDENTIFICATION**
**1.1. Product Identifier**
**Product Form:** Mixture

**Product Name:** Epinephrine Injection, USP

**Product Code:** 0517-1171-01; 0517-1171-10; 0517-3030-01

**1.2. Intended Use of the Product**
**Use of the Substance/Mixture:** Epinephrine injection is a non-selective alpha- and beta-adrenergic agonist indicated:

- For emergency treatment of allergic reactions (Type 1), including anaphylaxis.
- To increase mean arterial blood pressure in adult patients with hypotension associated with septic shock.

**1.3. Name, Address, and Telephone of the Responsible Party**
**Company**

American Regent, Inc.

5 Ramsey Road

P.O. Box 9001

Shirley, NY

1-800-645-1706

[www.americanregent.com](http://www.americanregent.com)
**1.4. Emergency Telephone Number**
**Emergency Number** : CHEMTREC 1-800-424-9300

**SECTION 2: HAZARDS IDENTIFICATION**
**2.1. Classification of the Substance or Mixture**
**GHS-US Classification**

Repr. 2 H361

Full text of hazard classes and H-statements : see section 16

**2.2. Label Elements**
**GHS-US Labeling**
**Hazard Pictograms (GHS-US)** :


GHS08

**Signal Word (GHS-US)** :

Warning

**Hazard Statements (GHS-US)** :

H361 - Suspected of damaging fertility or the unborn child.

**Precautionary Statements (GHS-US)** :

P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

P280 - Wear protective gloves, protective clothing, and eye protection.

P308+P313 - If exposed or concerned: Get medical advice/attention.

P405 - Store locked up.

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

**2.3. Other Hazards**

Exposure may aggravate pre-existing eye, skin, or respiratory conditions. Workers with cardiovascular and pulmonary disorders, hypertension, diabetes, and hyperthyroidism should minimize their exposure to this product. It is strongly recommended that pregnant workers not be exposed to this product.

**2.4. Unknown Acute Toxicity (GHS-US)**

No data available

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**
**3.1. Substance**

Not applicable

**3.2. Mixture**

Name	Product Identifier	%	GHS-US classification
Water	(CAS-No.) 7732-18-5	99.0	Not classified
Sodium chloride	(CAS-No.) 7647-14-5	0.9	Not classified

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Epinephrine	(CAS-No.) 51-43-4	0.1	Acute Tox. 3 (Oral), H301 Acute Tox. 2 (Dermal), H310 Acute Tox. 3 (Inhalation:dust,mist), H331 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Repr. 2, H361 STOT SE 3, H335 STOT RE 2, H373
Hydrochloric acid	(CAS-No.) 7647-01-0	Used to adjust pH	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401

Full text of H-phrases: see section 16

### SECTION 4: FIRST AID MEASURES

#### 4.1. Description of First-aid Measures

**First-aid Measures General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

**First-aid Measures After Inhalation:** When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

**First-aid Measures After Skin Contact:** Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

**First-aid Measures After Eye Contact:** Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

**First-aid Measures After Ingestion:** Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

#### 4.2. Most Important Symptoms and Effects Both Acute and Delayed

**Symptoms/Injuries:** There are potential chronic health effects to consider.

**Symptoms/Injuries After Inhalation:** Prolonged exposure may cause irritation.

**Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation. May cause an allergic reaction in sensitive individuals.

**Symptoms/Injuries After Eye Contact:** May cause slight irritation to eyes.

**Symptoms/Injuries After Ingestion:** Ingestion may cause adverse effects.

**Symptoms/Injuries Upon Accidental Exposure Through Injection:** See prescribing information.

**Chronic Symptoms:** Suspected of damaging fertility or the unborn child.

#### 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

### SECTION 5: FIRE-FIGHTING MEASURES

#### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Water spray, dry chemical, foam, carbon dioxide.

**Unsuitable Extinguishing Media:** Do not use a heavy water stream. Use of heavy stream of water may spread fire.

#### 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

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire.

**Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

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

**Hazardous Combustion Products:** Toxic vapors.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

#### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Do not get in eyes, on skin, or on clothing. Do not breathe vapor, mist or spray.

##### 6.1.1. For Non-Emergency Personnel

**Protective Equipment:** Use appropriate personal protective equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

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### 6.1.2. For Emergency Personnel

**Protective Equipment:** Equip cleanup crew with proper protection.

**Emergency Procedures:** Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

### 6.2. Environmental Precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and Materials for Containment and Cleaning Up

**For Containment:** Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

**Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

### 6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Precautions for Safe Handling:** Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes, on skin, or on clothing. Do NOT breathe (vapor, mist, and spray).

**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

**Storage Conditions:** Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store in controlled room temperature. Protect from light.

**NDC 0517-1071-05:** Store between 20° – 25°C (68° to 77°F) [See USP Controlled Room Temperature. Epinephrine is light sensitive. Protect from light and freezing.

**Incompatible Materials:** Strong oxidizers. Water reactive materials.

### 7.3. Specific End Use(s)

Epinephrine injection is a non-selective alpha- and beta-adrenergic agonist indicated:

- For emergency treatment of allergic reactions (Type 1), including anaphylaxis.
- To increase mean arterial blood pressure in adult patients with hypotension associated with septic shock.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH Ceiling (ppm)	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (ceiling) (mg/m <sup>3</sup> )	7 mg/m <sup>3</sup>
USA NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (Ceiling) (mg/m <sup>3</sup> )	7 mg/m <sup>3</sup>
USA OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm

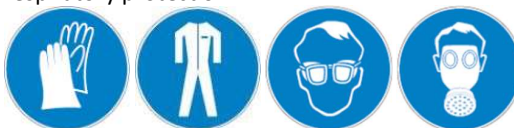
### 8.2. Exposure Controls

#### Appropriate Engineering Controls

: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

#### Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



#### Materials for Protective Clothing

: Chemically resistant materials and fabrics.

#### Hand Protection

: Wear protective gloves.

#### Eye and Face Protection

: Chemical safety goggles.

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- Skin and Body Protection** : Wear suitable protective clothing.
- Respiratory Protection** : If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.
- Other Information** : When using, do not eat, drink or smoke.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

- Physical State** : Liquid
- Appearance** : Clear, colorless
- Odor** : Odorless
- Odor Threshold** : No data available
- pH** : 2.2 – 5.0
- Evaporation Rate** : No data available
- Melting Point** : No data available
- Freezing Point** :  $\approx 32\text{ }^{\circ}\text{F}$  ( $0\text{ }^{\circ}\text{C}$ )
- Boiling Point** :  $\approx 212\text{ }^{\circ}\text{F}$  ( $100\text{ }^{\circ}\text{C}$ )
- Flash Point** : No data available
- Auto-ignition Temperature** : No data available
- Decomposition Temperature** : No data available
- Flammability (solid, gas)** : Not applicable
- Vapor Pressure** : No data available
- Relative Vapor Density at 20°C** : No data available
- Relative Density** : No data available
- Specific Gravity** :  $\approx 1$
- Solubility** : Water: Freely soluble
- Partition Coefficient: N-Octanol/Water** : No data available
- Viscosity** : No data available

### 9.2. Other Information No additional information available

## SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5. Incompatible Materials:** Strong oxidizers. Water reactive materials.
- 10.6. Hazardous Decomposition Products:** None expected under normal conditions of use.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on Toxicological Effects

**Acute Toxicity:** Not classified

Sodium chloride (7647-14-5)	
LD50 Oral Rat	3 g/kg
LD50 Dermal Rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation Rat	> 42 g/m <sup>3</sup> (Exposure time: 1 h)

Hydrochloric acid (7647-01-0)	
LD50 Dermal Rabbit	> 5010 mg/kg

Epinephrine (51-43-4)	
LD50 Dermal Rat	62 mg/kg
ATE (Oral)	100.00 mg/kg body weight
ATE (Dust/Mist)	0.50 mg/l/4h

**Skin Corrosion/Irritation:** Not classified

**pH:** 2.2 – 5.0

**Serious Eye Damage/Irritation:** Not classified

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pH: 2.2 – 5.0

**Respiratory or Skin Sensitization:** Not classified

**Germ Cell Mutagenicity:** Not classified

**Carcinogenicity:** Not classified

<b>Hydrochloric acid (7647-01-0)</b>	
<b>IARC group</b>	3

**Reproductive Toxicity:** Suspected of damaging fertility or the unborn child.

**Specific Target Organ Toxicity (Single Exposure):** Not classified

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified

**Aspiration Hazard:** Not classified

**Symptoms/Injuries After Inhalation:** Prolonged exposure may cause irritation.

**Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation. May cause an allergic reaction in sensitive individuals.

**Symptoms/Injuries After Eye Contact:** May cause slight irritation to eyes.

**Symptoms/Injuries After Ingestion:** Ingestion may cause adverse effects.

**Symptoms/Injuries Upon Accidental Exposure Through Injection:** See prescribing information.

**Chronic Symptoms:** Suspected of damaging fertility or the unborn child.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Ecology - General** : Not classified.

<b>Sodium chloride (7647-14-5)</b>	
<b>LC50 Fish 1</b>	5560 (5560 - 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
<b>EC50 Daphnia 1</b>	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
<b>LC50 Fish 2</b>	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
<b>EC50 Daphnia 2</b>	340.7 (340.7 - 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
<b>NOEC Chronic Fish</b>	252 mg/l (Species: Pimephales promelas)

<b>Hydrochloric acid (7647-01-0)</b>	
<b>LC50 Fish 1</b>	7.45 mg/l (Species: Oncorhynchus mykiss - Exposure time: 96h)

### 12.2. Persistence and Degradability

<b>Epinephrine Injection, USP</b>	
<b>Persistence and Degradability</b>	Not established.

### 12.3. Bioaccumulative Potential

<b>Epinephrine Injection, USP</b>	
<b>Bioaccumulative Potential</b>	Not established.

<b>Sodium chloride (7647-14-5)</b>	
<b>BCF Fish 1</b>	(no bioaccumulation)

**12.4. Mobility in Soil** No additional information available

### 12.5. Other Adverse Effects

**Other Information** : Avoid release to the environment.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste Treatment Methods

**Waste Disposal Recommendations:** Dispose of contents/container in accordance with local, regional, national, and international regulations.

**Additional Information:** Container may remain hazardous when empty. Continue to observe all precautions.

**Ecology - Waste Materials:** Avoid release to the environment.

## SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

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- 14.1. In Accordance with DOT** Not regulated for transport  
**14.2. In Accordance with IMDG** Not regulated for transport  
**14.3. In Accordance with IATA** Not regulated for transport

### SECTION 15: REGULATORY INFORMATION

#### 15.1. US Federal Regulations

<b>Epinephrine Injection, USP</b>	
<b>SARA Section 311/312 Hazard Classes</b>	Delayed (chronic) health hazard
<b>Sodium chloride (7647-14-5)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Hydrochloric acid (7647-01-0)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory Listed on the United States SARA Section 302 Subject to reporting requirements of United States SARA Section 313	
<b>CERCLA RQ</b>	5000 lb
<b>SARA Section 302 Threshold Planning Quantity (TPQ)</b>	500 lb (gas only)
<b>SARA Section 313 - Emission Reporting</b>	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)
<b>Water (7732-18-5)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Epinephrine (51-43-4)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>CERCLA RQ</b>	1000 lb

#### 15.2. US State Regulations

<b>Hydrochloric acid (7647-01-0)</b>
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List U.S. - Pennsylvania - RTK (Right to Know) List
<b>Epinephrine (51-43-4)</b>
U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List U.S. - Pennsylvania - RTK (Right to Know) List

### SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

<b>Date of Preparation or Latest Revision</b>	: 09/12/2023
<b>Other Information</b>	: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

#### GHS Full Text Phrases:

Acute Tox. 2 (Dermal)	Acute toxicity (dermal) Category 2
Acute Tox. 3 (Inhalation: dust, mist)	Acute toxicity (inhalation: dust, mist) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Met. Corr. 1	Corrosive to metals Category 1
Repr. 2	Reproductive toxicity Category 2
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H290	May be corrosive to metals

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H301	Toxic if swallowed
H310	Fatal in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H331	Toxic if inhaled
H335	May cause respiratory irritation
H361	Suspected of damaging fertility or the unborn child
H373	May cause damage to organs through prolonged or repeated exposure
H401	Toxic to aquatic life
H402	Harmful to aquatic life

Refer to American Regent prescribing information for further information at: <http://www.americanregent.com/AllProducts.aspx>

*The information above is believed to be accurate and represents the best information currently available to American Regent. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall American Regent, Inc., its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if American Regent, Inc. has been advised of the possibility of such damages.*

SDS US (GHS HazCom)