

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Vasopressin Injection, USP

Product Code: 0517-1020-25; 0517-1020-01

1.2. Intended Use of the Product

Use of the Substance/Mixture: Vasopressin injection is indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines.

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

Company

American Regent, Inc.

5 Ramsey Road

Shirley, NY 11967

1-800-645-1706

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

Not classified

2.2. Label Elements

GHS-US Labeling

No labeling applicable

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

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	Synonyms	Product Identifier	%	GHS US classification
Water for Injection	AQUA / Aqua	(CAS-No.) 7732-18-5	98.6	Not classified
Sodium chloride	Sea salt / Sodium chloride (NaCl) / SODIUM CHLORIDE / Sodium salt of hydrochloric acid / Salt / SEA SALT	(CAS-No.) 7647-14-5	0.9	Not classified
2-Propanol, 1,1,1-trichloro-2-methyl-	Acetone chloroform / Anhydrous chlorobutanol / Chlorbutanol / Chlorobutanol / Chlorobutanol, anhydrous / Propan-2-ol, 1,1,1-trichloro-2-methyl- / 2-Propanol, 2-methyl-1,1,1-trichloro- / 1,1,1-Trichloro-2-methyl-2-propanol / Chlorbutol / CHLOROBUTANOL / 1,1,1-Trichloro-2-methylpropanol-2 / 1,1,1-Trichloro-2-methylpropan-2-ol	(CAS-No.) 57-15-8	0.5	Acute Tox. 4 (Oral), H302
Vasopressin	Argipressin/1,2-Dithia-5,8,11,14,17-pentaazacycloeicosane-10-proprionamide, 19-amino-13-benzyl-7-(carbamoylmethyl)-4-[2-[[1-[(carbamoylmethyl)carbamoyl]-4-guanidinobutyl]carbamoyl]-1-pyrrolidinylcarbonyl]-16-p-hydroxybenzyl-6,9,12,15,18-pentaoxo- / 3-(Phenylalanine)-8-arginineoxytocin / 8-L-Arginine-vasopressin / Arg8-vasopressin / Arginine antidiuretic hormone / Arginine-8-vasopressin / Arginine-vasopressin / AVP / Oxytocin, 3-(L-phenylalanine)-8-L-arginine- / Pitressin / Vasopressin, 8-L-arginine- / [8-Arginine]vasopressin	(CAS-No.) 113-79-1	0.005	Repr. 2, H361 STOT RE 2, H373
Acetic acid	Acetic acid, glacial / Ethanoic acid / Ethylic acid / Vinegar acid / ACETIC ACID / Acetic acid solution / Acetic acid ...%	(CAS-No.) 64-19-7	Used to adjust pH	Flam. Liq. 3, H226 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402

Full text of H-phrases: see section 16

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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 5 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 if irritation develops or persists.

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: Not expected to present a significant hazard under anticipated conditions of normal use.

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

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

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

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

Chronic Symptoms: None known.

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: Use extinguishing media appropriate for surrounding fire.

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: Product is 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: Sodium oxides. Chlorine. Carbon oxides (CO, CO₂). Nitrogen oxides. Sulfur oxides.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray).

6.1.1. For Non-Emergency Personnel

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

Emergency Procedures: Evacuate unnecessary personnel.

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.

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SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

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: Store in a dry, cool place. Keep container closed when not in use. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

Storage Temperature: Store between 2°C and 8°C (36°F and 46°F). Do not freeze. Storage is permitted for up to 12 months at controlled room temperature (USP) 20°C to 25°C (68°F to 77°F) within the expiry date. (See USP Controlled Room Temperature).

7.3. Specific End Use(s)

Pharmaceutical.

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).

Acetic acid (64-19-7)		
USA ACGIH	ACGIH TWA (ppm)	10 ppm
USA ACGIH	ACGIH STEL (ppm)	15 ppm
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	25 mg/m ³
USA NIOSH	NIOSH REL (TWA) (ppm)	10 ppm
USA NIOSH	NIOSH REL (STEL) (mg/m ³)	37 mg/m ³
USA NIOSH	NIOSH REL (STEL) (ppm)	15 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (TWA) (mg/m ³)	25 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	10 ppm

8.2. Exposure Controls

Appropriate Engineering Controls

- : Suitable eye/body wash equipment should be available in the 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.



Materials for Protective Clothing

- : Chemically resistant materials and fabrics.

Hand Protection

- : Wear protective gloves.

Eye and Face Protection

- : Chemical safety goggles.

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 or practically colorless
Odor	: Faint characteristic odor
Odor Threshold	: No data available
pH	: 2.5 - 4.5
Evaporation Rate	: No data available
Melting Point	: ≈ 32 °F (0 °C)

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Freezing Point	: $\approx 32^{\circ}\text{F}$ (0°C)
Boiling Point	: $\approx 212^{\circ}\text{F}$ (100°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	: ≈ 1
Solubility	: Freely Soluble in water
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 acids, strong bases, strong oxidizers.
- 10.6. Hazardous Decomposition Products:** Thermal decomposition may produce: Nitrogen oxides. Carbon oxides (CO , CO_2). Sulfur oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity: Not classified

Sodium chloride (7647-14-5)	
LD50 Oral Rat	3550 mg/kg (Species: Wistar)
LD50 Dermal Rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation Rat	> 42 g/m ³ (Exposure time: 1 h)
2-Propanol, 1,1,1-trichloro-2-methyl- (57-15-8)	
LD50 Oral Rat	510 mg/kg
Acetic acid (64-19-7)	
LD50 Oral Rat	3310 mg/kg

Skin Corrosion/Irritation: Not classified (pH: 2.5 - 4.5)

Serious Eye Damage/Irritation: Not classified (pH: 2.5 - 4.5)

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: 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 After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

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

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

Chronic Symptoms: None known.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Sodium chloride (7647-14-5)	
LC50 Fish 1	5560 (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])

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EC50 Daphnia 2	340.7 (340.7 - 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
NOEC Chronic Fish	252 mg/l (Species: Pimephales promelas)
Acetic acid (64-19-7)	
LC50 Fish 1	79 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 1	65 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
LC50 Fish 2	75 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

12.2. Persistence and Degradability

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Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Vasopressin Injection, USP	
Bioaccumulative Potential	Not established.
Sodium chloride (7647-14-5)	
BCF Fish 1	(no bioaccumulation)
Acetic acid (64-19-7)	
Log Pow	-0.31 (at 20 °C)

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.

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.

- 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

Sodium chloride (7647-14-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
2-Propanol, 1,1,1-trichloro-2-methyl- (57-15-8)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Acetic acid (64-19-7)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	5000 lb
Water for Injection (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State Regulations

Acetic acid (64-19-7)
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

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

Date of Preparation or Latest Revision : 01/21/2022
Other Information : 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:

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Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Flam. Liq. 3	Flammable liquids Category 3
Repr. 2	Reproductive toxicity Category 2
Skin Corr. 1A	Skin corrosion/irritation Category 1A
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
H226	Flammable liquid and vapor
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H361	Suspected of damaging fertility or the unborn child
H373	May cause damage to organs through prolonged or repeated exposure
H402	Harmful to aquatic life

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)