

SECTION 1: IDENTIFICATION**1.1. Product Identifier****Product Form:** Mixture**Product Name:** Vasopressin Injection, USP**Synonyms:**

Vasopressin Injection, USP (SDV) – Preservative Free – PC 930101 – 1 mL fill per vial

Vasopressin Injection, USP (MDV) – Preserved – PC 930110- 10 mL fill per vial

1,2-Dithia-5,8,11,14,17-pentaazacycloeicosane-10-propionamide, 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-

injection

3-(Phenylalanine)-8-arginineoxytocin injection

[8-Arginine]vasopressin injection

8-L-Arginine-vasopressin injection

Arg8-vasopressin injection

Arginine-8-vasopressin injection

Arginine antidiuretic hormone injection

Arginine-vasopressin injection

Argipressin injection

AVP injection

Oxytocin, 3-(L-phenylalanine)-8-L-arginine- injection

Pitressin injection

Vasopressin, 8-L-arginine- injection

1.2. Intended Use of the Product

For intravenous administration to increase blood pressure in adults with vasodilatory shock (e.g post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines.

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

Fresenius Kabi USA
3159 Staley Road
Grand Island, NY 14072
(716) 773-0800

Distributor

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
<http://www.fresenius-kabi.com/us/>

1.4. Emergency Telephone Number

Emergency Number : VelocityEHS
(800)255-3924 (North America)
+1 (813)248-0585 (International)

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

Not classified

2.2. Label Elements

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GHS-US/CA Labeling

No labeling applicable according to 29 CFR 1910.1200 and the Hazardous Products Regulations (HPR) SOR/2015-17.

2.3. Other Hazards

No additional information available

2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Water	AQUA	(CAS-No.) 7732-18-5	> 99	Not classified
Chlorobutanol **	Acetone chloroform / Anhydrous chlorobutanol / Chlorobutanol / 2-Propanol, 1,1,1-trichloro-2-methyl- / 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 / 1,1,1-Trichloro-2-methylpropanol-2 / 1,1,1-Trichloro-2-methylpropan-2-ol / 2-Propanol, 1,1,1-trichloro-2-methyl-hydrate	(CAS-No.) 57-15-8	0.5	Acute Tox. 4 (Oral), H302
Sodium acetate trihydrate	Acetate, sodium, trihydrate / Acetic acid, sodium salt, trihydrate / Sodium acetate-3-hydrate / Acetic acid, sodium salt, hydrate (1:1:3) / Sodium acetate	(CAS-No.) 6131-90-4	0.14	Combustible Dust
Hydrochloric acid	Hydrochloric acid, anhydrous / Muriatic acid / Hydrogen chloride	(CAS-No.) 7647-01-0	< 0.1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401
Sodium hydroxide	Sodium hydroxide (Na(OH)) / Caustic soda / Lye	(CAS-No.) 1310-73-2	< 0.1	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 1, H370 Aquatic Acute 3, H402
Vasopressin	1,2-Dithia-5,8,11,14,17-pentaazacycloeicosane-10-propionamide, 19-amino-13-benzyl-7-(carbamoylmethyl)-4-[2-[[1-[(carbamoylmethyl)carbamoyl]-4-guanidinobutyl]carbamoyl]-1-pyrrolidinylcarbonyl]-16-p-hydroxybenzyl-6,9,12,15,18-penta-oxo- / 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 / Argipressin	(CAS-No.) 113-79-1	0.004	Acute Tox. 3 (Inhalation), H331 Repr. 1B, H360 STOT SE 1, H370

Full text of H-statements: see section 16

*Percentages are listed in weight by weight percentage (w/w%)

**Preservative. Not present in PC 930101

SECTION 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 the label where possible).

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

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Skin Contact: Remove contaminated clothing. Wash immediately with plenty of soap and water. Obtain medical attention if irritation develops or persists.

Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Common clinical side effects include: Cardiovascular - Cardiac arrest, circumoral pallor, arrhythmias, decreased cardiac output, angina, myocardial ischemia, peripheral vasoconstriction, and gangrene. Gastrointestinal - Abdominal cramps, nausea, vomiting, passage of gas. Nervous System - Tremor, vertigo, "pounding" in head. Respiratory - Bronchial constriction. Skin and Appendages - Sweating, urticaria, cutaneous gangrene. Overdosage - Water intoxication.

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: Prolonged exposure may cause skin irritation.

Eye Contact: Prolonged exposure may cause slight irritation to eyes.

Ingestion: Ingestion of large quantities may have adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

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 suitable for surrounding type of fire.

Unsuitable Extinguishing Media: None known.

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: None known

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

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: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, 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: Store at 2-8 °C / 36-46 °F. Do not freeze. Vials may be held up to 12 months upon removal from refrigeration to room temperature storage conditions (20-25 °C [68-77 °F], [see USP Controlled Room Temperature]), anytime within the labeled shelf life. Once removed from refrigeration, unopened vial should be marked to indicate the revised 12 month expiration date. If the manufacturer's original expiration date is shorter than the revised expiration date, then the shorter date must be used. Do not use Vasopressin injection beyond the manufacturer's expiration date stamped on the vial.

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

Storage Temperature: 2-8 °C (36-46 °F). Do not freeze.

7.3. Specific End Use(s)

For intravenous administration to increase blood pressure in adults with vasodilatory shock (e.g post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines.

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), OSHA (PEL), or Canadian provincial governments.

Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH OEL Ceiling	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA OSHA	OSHA PEL Ceiling	7 mg/m ³
USA OSHA	OSHA PEL C	5 ppm
USA NIOSH	NIOSH REL Ceiling	7 mg/m ³
USA NIOSH	NIOSH REL C	5 ppm
USA IDLH	IDLH	50 ppm
Alberta	OEL C	3 mg/m ³
Alberta	OEL Ceiling	2 ppm
British Columbia	OEL Ceiling	2 ppm
Manitoba	OEL Ceiling	2 ppm
New Brunswick	OEL C	7.5 mg/m ³
New Brunswick	OEL Ceiling	5 ppm
Newfoundland & Labrador	OEL Ceiling	2 ppm
Nova Scotia	OEL Ceiling	2 ppm
Nunavut	OEL Ceiling	2 ppm
Northwest Territories	OEL Ceiling	2 ppm
Ontario	OEL Ceiling	2 ppm
Prince Edward Island	OEL Ceiling	2 ppm
Québec	Plafond OEL Ceiling	2 ppm
Saskatchewan	OEL Ceiling	2 ppm
Yukon	OEL C	7 mg/m ³
Yukon	OEL Ceiling	5 ppm
Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH OEL Ceiling	2 mg/m ³
USA OSHA	OSHA PEL TWA	2 mg/m ³
USA NIOSH	NIOSH REL Ceiling	2 mg/m ³
USA IDLH	IDLH	10 mg/m ³
Alberta	OEL C	2 mg/m ³

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British Columbia	OEL C	2 mg/m ³
Manitoba	OEL C	2 mg/m ³
New Brunswick	OEL C	2 mg/m ³
Newfoundland & Labrador	OEL C	2 mg/m ³
Nova Scotia	OEL C	2 mg/m ³
Nunavut	OEL C	2 mg/m ³
Northwest Territories	OEL C	2 mg/m ³
Ontario	OEL C	2 mg/m ³
Prince Edward Island	OEL C	2 mg/m ³
Québec	Plafond OEL Ceiling	2 mg/m ³
Saskatchewan	OEL C	2 mg/m ³
Yukon	OEL C	2 mg/m ³

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	: Colorless liquid
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: 3.8
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Lower Flammable Limit	: No data available
Upper Flammable Limit	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: ≈ 1
Density	: 0.9967 – 0.9982 g/ml
Specific Gravity	: No data available
Solubility	: Water: Soluble
Partition Coefficient: N-Octanol/Water	: No data available

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Viscosity : No data 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: Carbon oxides (CO, CO₂). Chlorine compounds. Nitrogen oxides. Sulfur oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Likely routes of exposure: Eye contact. Dermal. Ingestion.

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data: No additional information available

Skin Corrosion/Irritation: Not classified

Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single 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: Prolonged exposure may cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion of large quantities may have adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Hydrochloric acid (7647-01-0)	
LD50 Dermal Rabbit	> 5010 mg/kg
Sodium hydroxide (1310-73-2)	
LD50 Oral Rat	325 mg/kg
Chlorobutanol (57-15-8)	
LD50 Oral Rat	510 mg/kg

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

Hydrochloric acid (7647-01-0)	
LC50 Fish	7.45 mg/l (Species: Oncorhynchus mykiss - Exposure time: 96h)
Sodium hydroxide (1310-73-2)	
LC50 Fish	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Crustacea	40 mg/l

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12.2. Persistence and Degradability

Vasopressin Injection, USP	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Vasopressin Injection, USP	
Bioaccumulative Potential	Not established.
Chlorobutanol (57-15-8)	
Partition coefficient n-octanol/water (Log POW)	2.16 (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, territorial, provincial, 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

14.4. In Accordance with TDG

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
Listed on the United States SARA Section 302	
Subject to reporting requirements of United States SARA Section 313	
CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)
Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
CERCLA RQ	1000 lb
Chlorobutanol (57-15-8)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	

15.2. US State Regulations

Hydrochloric acid (7647-01-0)
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List
U.S. - Massachusetts - Right To Know List
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

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Sodium hydroxide (1310-73-2)

U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List
U.S. - Massachusetts - Right To Know List
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

15.3. Canadian Regulations

Water (7732-18-5)

Listed on the Canadian DSL (Domestic Substances List)

Hydrochloric acid (7647-01-0)

Listed on the Canadian DSL (Domestic Substances List)

Sodium hydroxide (1310-73-2)

Listed on the Canadian DSL (Domestic Substances List)

Chlorobutanol (57-15-8)

Listed on the Canadian DSL (Domestic Substances List)

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

Date of Preparation or Latest Revision : 05/25/2023

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

GHS Full Text Phrases:

H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H331	Toxic if inhaled
H335	May cause respiratory irritation
H360	May damage fertility or the unborn child
H370	Causes damage to organs
H401	Toxic to aquatic life
H402	Harmful to aquatic life

NFPA Health Hazard : 0 - Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials.

NFPA Fire Hazard : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

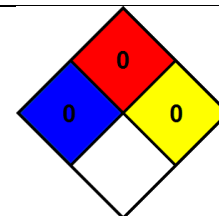
NFPA Reactivity Hazard : 0 - Material that in themselves are normally stable, even under fire conditions.

HMIS III Rating

Health : 0 Minimal Hazard

Flammability : 0 Minimal Hazard

Physical : 0 Minimal Hazard



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.