CAPLIN STERILES

Caplin Steriles Limited
(A Subsidiary of Caplin Point Laboratories Limited)
Regd. office: Ashvich Tower, 3rd Floor, No.3, Developed Plots Industrial Estate, Perungudi, Chennai – 600096. INDIA.
Phone : +91 44 2496 8000 / +91 80127 72888 / +91 44 7114 8000
CIN No: U24304TN2018PLC126270
E-mail : info@caplinsteriles.net / Website : www.caplinsteriles.net

SAFETY DATA SHEET

Desmopressin Acetate Injection 4mcg/mL & 40mcg/mL

SECTION 1: IDENTIFICATION

Product Identifier

Product Form:	Mixture
Product Name:	Desmopressin Acetate Injection 4mcg/mL & 40mcg/mL (4mcg/mL)
Intended Use of the Product	Pharmaceutical preparation
Name, Address, and Telephone of the Responsible Party	CAPLIN STERILES LTD Ashvich Tower, R&D unit 1st and 2nd Floor, No.3, Developed Plots Industrial Estate, Perungudi, Chennai. 600096.Tamil Nadu. INDIA.
Emergency Telephone Number	+91 44 2496 8000 +91 80127 72888 +91 44 7114 8000

SECTION 2: HAZARDS IDENTIFICATION

2.1.Classification of the Substance or Mixture

GHS-US/CA Classification

Not classified

2.2. Label Elements

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

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

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 / water	(CAS-No.) 7732-18-5	97.355	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

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Chorobutanol (Hemihydrate)	1,1,1-Trichloro-2-methyl-2-propanol hemihydrate Chlorbutanol Hemihydrate	(CAS-No.) 6001-64-5	0.525	Not classified
Desmopressin Acetate	Vasopressin, 1-(3-mercaptopropanoic acid)-8-D-arginine-, monoacetate (salt), trihydrate / 1-(3-Mercaptopropanoic acid)-8-D-argininevasopressin monoacetate (salt), trihydrate / desmopressin acetate	(CAS-No.) 62357-86 2	0.000 4	Not Classified

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volumeby volume percentage (v/v%).

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). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.**Inhalation:** When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention ifirritation 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: Not expected to present a significant hazard under anticipated conditions of normal use.

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: Prolonged exposure may cause skin irritation.

Eye Contact: May cause slight irritation to eyes.

Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions.

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 considered flammable but may burn at high temperatures.

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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: Carbon monoxide. Carbon dioxide. Sodium oxides. Chlorinated compounds.

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). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

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. Absorb liquid components with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). 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

Additional Hazards When Processed: Material may be biologically contaminated with pathogenic organisms.
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° to 8°C (36° to 46°F) [Do not Freeze].

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

7.3.Specific End Use(s)

No additional information available

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.

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.

Hand Protection: Wear protective gloves.
Eye and Face Protection: Safety glasses with side-shields.

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.
Environmental Exposure Controls: Avoid unnecessary release into the environment.
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 liquid
Odor	:	Odorless
Odor Threshold	:	No data available
pH	:	3.5 – 6.0
Evaporation Rate	:	No data available
Melting Point	:	No data available
Freezing Point	:	No data available
Boiling Point	:	≈100 °C (212 °F)
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

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Vapor Pressure	:	No data available
Relative Vapor Density at 20°C	:	No data available
Relative Density	:	No data available
Specific Gravity	:	No data available
Solubility	:	Soluble in water.
Partition Coefficient: N-Octanol/Water	:	No data available
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, CO_2). Sodium oxides. Chlorine compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects - Product

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

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

pH: 3.5 – 6

Eye Damage/Irritation: Not classified

pH: 3.5 – 6

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

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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 of large quantities may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

Information of Toxicological effect on Ingredient:

LD50 and LC50 Data:

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 mg/l (Exposure time: 1 h)
Hydrochloric acid (7647-01-0)	
LD50 Oral Rat	238 – 277 mg/kg
LD50 Dermal Rabbit	> 5010 mg/kg
LC50 Inhalation Rat	1.68 mg/l (Exposure time: 1 h)
Hydrochloric acid (7647-01-0)	
IARC Group	3

SECTION 12: ECOLOGICAL INFORMATION

12.1 toxicity

Sodium chloride (7647-14-5)	
LC50 Fish 1	5560 (5560 – 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 - Crustacea [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 - Crustacea [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)
Hydrochloric acid (7647-01-0)	
LC50 Fish 1	7.45 mg/l (Species: Oncorhynchus mykiss - Exposure time: 96h)

12.2. Persistence and Degradability

Desmopressin Acetate Injection, 4mcg/mL, 1 or 10 mL per vial	
Persistence and Degradability	Expected to be biodegradable.

12.3. Bioaccumulative Potential

Desmopressin Acetate Injection, 4mcg/mL, 1 or 10 mL per vial	
Bioaccumulative Potential	Not expected to bioaccumulate.
2-Propanol, 1,1,1-trichloro-2-methyl-, hemihydrate (6001-64-5)	
Partition coefficient n-octanol/water (Log Pow)	2.03
Sodium chloride (7647-14-5)	
BCF Fish 1	(no bioaccumulation)

12.4. Mobility in Soil

Desmopressin Acetate Injection, 4mcg/mL, 1 or 10 mL per vial	
Ecology - Soil	Leaches into groundwater.

12.5. Other Adverse Effects

Other Adverse Effects: None known.

Other Information: Avoid unnecessary release into the environment.

SAFETY DATA SHEET

Desmopressin Acetate Injection 4mcg/mL & 40mcg/mL

SECTION 13: DISPOSAL COSIDERATION

Waste treatment methods

Waste Treatment Methods: Can be landfilled or incinerated, when in compliance with local regulations.

Sewage Disposal Recommendations: Do not dispose of waste into sewer. Do not empty into drains.

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

Additional Information: Biologically contaminated materials should be incinerated.

Ecology - Waste Materials: Avoid unnecessary release into 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.

In Accordance with DOT Not regulated for transport
In Accordance with IMDG Not regulated for transport
In Accordance with IATA Not regulated for transport
In Accordance with TDG Not regulated for transport

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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 - Status: Active
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)

15.2. US State Regulations

Desmopressin Acetate Injection, 4mcg/mL, 1 or 10 mL per vial ()
State or local 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

15.3. Canadian Regulations

Sodium chloride (7647-14-5)
Listed on the Canadian DSL (Domestic Substances List)
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)

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SECTION 16: ADDITIONAL INFORMATION

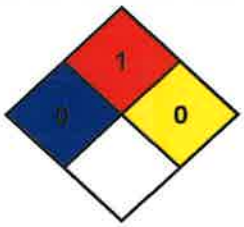
Date of SDS Creation : 02/12/2025

Version : 00

Prepared By : Caplin Steriles Limited

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:



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

NFPA Fire Hazard : 1 - Materials that must be preheated before ignition can occur.

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

HMIS III Rating

Health : 0 Minimal Hazard - No significant risk to health
Flammability : 1 Slight Hazard
Physical : 0 Minimal Hazard
Personal protection : B

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

---End of Safety Data Sheet---

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