SAFETY DATA SHEET

Vasopressin Injection USP, 20 Units ML

SECTION – 1: IDENTIFICATION

Name of the product	Vasopressin Injection USP, 20 Units ML Vials
Name of the organization	Amneal Pharmaceuticals Pvt. Ltd. Plot No. 15, 16, 17, PHARMEZ- SEZ, Sarkhej-Bavla Highway, Ta. Sanad , Dist. Ahmeddabad- 382220, Gujarat, India.
Emergency contact numbers	Phone : 91 2714 671600
Synonyms for drug used in the Vials	For vasopressin: 8-Arginine vasopressin; argipressin
Therapeutic use	Specified quality tests and assay use only

SECTION - 2: HAZARDS IDENTIFICATION

Principal Hazards of the product	Not a hazardous substance or mixture. It is in vials as a liquid form.
Harmful Effect of the drug on Health	May Be Harmful if Ingested Or Inhaled in large quantity.
Effects on the Environment	Product is Biodegradable.
Physical & Chemical Hazards	Thermal Decomposition can generate NOx, COx, etc.

ROUTE OF EXPOSURE

Hazard Statement:

P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P405 - Store locked up
P501 - Dispose of contents/container to an approved waste disposal plant

Potential Acute Health Effects:
Hazardous in case of ingestion.

Hazardous in case of skin contact (irritant, permeator), of eye contact (irritant).

Slightly hazardous in case of inhalation.

Potential Chronic Health Effects:

Very hazardous in case of ingestion. Hazardous in case of skin contact (irritant), of eye contact (Irritant). Slightly hazardous in case of inhalation.

CARCINOGENIC EFFECTS: Not available.

MUTAGENIC EFFECTS: Not available.

TERATOGENIC EFFECTS: Not available.

DEVELOPMENTAL TOXICITY: Not available.

Other hazards: Vasopressin is a potent antidiuretic and vasoconstricting agent. The most common adverse effects reported with use (up to ~100 µg/day) include marked pallor, pounding headache, vertigo, sweating, tremor, and gastrointestinal disturbances (nausea, vomiting, diarrhea, burping, cramps, and a desire to defecate).

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

SECTION – 3: COMPOSITION/INFORMATION ON INGREDIENTS

Usual Chemical Name of the drug used in the product		Vasopressin	
CAS Number for the drug used in the Vials: Vasopressin Chlorobutanol		113-79-1 57-15-8	
Ingredient Contributing to Hazard			
Ingredients of the product	**Approximate Percent by Weight Qty. (Mg) /Unit**	Class	Risk Phrases
Vasopressin USP	0.0361	Not known	Not known
Chlorobutanol NF (anhydrous)	50.00	Not known	Not known

*** These materials are considered non-hazardous under EU, US and Canadian regulations.**

NOTE: This MSDS is written to address potential worker health and safety issues associated with the handling of the formulated final product which is a vials, e.g., during the transportation, distribution, and use by medical personnel. For worker health and safety information during the manufacture of Leuprolide Acetate Injection, please refer to the MSDS on each component.

SECTION - 4: FIRST-AID MEASURES

Contact With Skin	May cause an allergic skin reaction. Wash the effected part of the skin with plenty of water. Remove contaminated clothing and wash before use. Obtain medical attention, if skin reaction occurs.
Contact With Eyes	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Check for and remove any contact lenses. If pain persists or recurs get medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation	Use proper PPE while handling it. Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Instruction for the physician	In case of inhalation of decomposition products in a fire, symptoms may be delayed. Treat according to symptoms. Keep the victim under medical surveillance.
Protection for first aiders	Use mask. Safety glasses and gloves. Wash the hand with plenty of water.

SECTION - 5: FIRE-FIGHTING MEASURES

Specific hazards	No specific fire or explosion hazard.
Fire extinguishing media	Water, Dry chemical, Carbon Dioxide. For lager fire use water spray or standard foam. Use water delivered as a fine spray to control fire & cool adjacent area. Do not use water jet.
Protection equipment	Fire Fighting with the use of self-content breathing apparatus, appropriate fire suit, boots, helmet and rubber hand gloves.
Other advice	Cool the containers in the vicinity with sprayed water or move the containers form fire area, if possible.

SECTION – 6: ACCIDENTAL RELEASE MEASURES

Personal precautions	Avoid direct contact. Wear the Personal protective equipment.
Precautions for environmental Protection	Keep out of drains; prevent entry into the natural environment.
Cleaning methods	Use appropriate tools to put the spilled liquid in a convenient waste disposal container. Dispose the product as Hazardous waste and Incinerate in an approved facility. Waste must be disposed of in accordance with state and local environmental control regulations.

SECTION -7: HANDLING AND STORAGE

Handling Appropriate technical measures	Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk; evaporate the residue under a fume hood.
Storage Recommended storage conditions	Must be refrigerated at 2° to 8°C (36° to 46°F). [See USP controlled room temperature] in closed container. Protect from light. Keep container dry. Keep in a cool place. Keep container tightly closed. Keep in a cool, well-ventilated place. Combustible materials should be stored away from extreme heat and away from strong oxidizing agents.
Recommended packaging materials	Vials in Carton in Corrugated boxes (As per label instuctions)
Precautions	Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes.

SECTION - 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Technical measures	Handle only with an appropriate nose mask and in a well-ventilated area.
Respiratory protection	Respiratory protection like mask is required.
Hand protection	Gloves
Eye protection	Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 66(EU). Safety glasses
Body and skin protection	Standard working suit
Specific safety protection	Do not drink or eat during handling.
Exposure limits	Not available

SECTION - 9: PHYSICAL AND CHEMICAL PROPERTIES

Size/shape/colour description of the vials or Appearance	Clear, colorless solution
Form	Liquid
Odor	Faint, characteristic odor
PH	No data available
Water Solubility	Soluble in water
Boiling Point	No data available
Melting Point	No data available
Molecular Weight	No data available
Vapor Pressure	Nil
Specific gravity	No data available
Percent Volite	Nil
Vapor density	Nil
Evaporation	Nil

SECTION - 10: STABILITY AND REACTIVITY

Stability	Material is stable under normal conditions.
Conditions to avoid	Heat and flame.
Materials to avoid	As a precautionary measure, keep away from strong oxidizers
Hazardous decomposition Products	No data available
Incompability	As a precautionary measure, keep away from acids
Hazardous Polymerization	Will not occur

SECTION - 11: TOXICOLOGICAL INFORMATION

Routes of Entry:	Dermal contact. Eye contact. Ingestion.
Toxicity to Animals: Acute	Intravenous LD 50 = 220 Unit/Kg. [Mouse]
Chronic Effects on Humans:	The substance is toxic to lungs and Mucus membranes.
Other Toxic Effects on Humans:	Very hazardous in case of ingestion. Hazardous in case of skin contact (irritant, permeator). Slightly hazardous in case of inhalation.
Special Remarks on Toxicity to Animals:	Not available.
Special Remarks on Chronic Effects on Humans:	No known significant effects or critical hazards.
Special Remarks on other Toxic Effects on Humans:	No known significant effects or critical hazards.

SECTION - 12: ECOLOGICAL INFORMATION

Persistence / degradation of the drug	The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.
Bioaccumulation	No data available
Aquatic Toxicity	No data available

SECTION - 13: DISPOSAL CONSIDERATIONS

Product disposal	Disposed of in accordance with state and local environmental control regulations.
Disposal of contaminated Packaging & Personal protective equipment	As Above

SECTION - 14: TRANSPORT INFORMATION

Land	RTMD	Class	Not dangerous goods
Rail	RID/ADR	Class	Not dangerous goods
Sea	IMCO/IMDG	Class	Not dangerous goods
Air	OACI/IATA	Class	Not dangerous goods
River	DON/AONR	Class	Not dangerous goods
UN proper shipping name DOT / IATA		Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.	

SECTION - 15: REGULATORY INFORMATION

Eec regulations	US federal regulations CERCLA/SARA Hazardous Substances - Not listed
Federal and State Regulations:	TSCA 8(b) inventory: No products were found.
Protective Equipment:	Gloves. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate. Splash goggles.
Hazard category	Not applicable
Hazard Class	Not applicable
California Proposition 65	Not listed
U.S. OSHA Classification	TSCA inventory list: The product is exempted from TSCA, It is FDA regulated
Full text H phrases and GHS classifications	ATI3 - Acute Toxicity (Inhalation) Category 3. H331 - Toxic if inhaled. RT1B Reproductive Toxicity Category 1B. H360Df – May damage the unborn child. Suspected of damaging fertility.

SECTION - 16: OTHER INFORMATION

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD50	Dosage producing 50% mortality
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

EC50 = concentration that causes an effect in 50% of test organisms
LC50 = concentration that is lethal in 50% of test organisms
NOEC = No Observed Effect Concentration

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Further information	Not available

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----------End of SDS -------

Bharat Patel - EHS

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