

**MATERIAL SAFETY DATA SHEET****1. PRODUCT IDENTIFICATION**

Drug Product : Desmopressin Acetate Injection USP, 4 mcg/mL, 10 mL per vial

Synonym : Desmopressin Acetate Injection

Note : This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Product Use : Medical Treatment: Antidiuretic
Chemical Family : Synthetic hormone
How Supplied : 4 ug/mL, 10 mL per vial

Company Name : Sun Pharmaceutical Industries Ltd.
Acme Plaza, Andheri-Kurla Road, Andheri (E)
Mumbai – 400 059, INDIA

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS Registry No	Percentage (w/w)	Exposure limit in AIR				
			AACGIIH		OSHA		Other
			TLV	CEIL	PEL	CEIL	
Desmopressin Acetate, USP	62357-86-2	0.0004	NE	NE	NE	NE	NE
Chlorobutanol, NF	6001-64-5	0.5	NE	NE	NE	NE	NE
Sodium Chloride, USP	7647-14-5	0.9	NE	NE	NE	NE	NE
Hydrochloric Acid, NF	7647-01-0	Trace	NE	5 ppm	NE	5 ppm	NE
Water for Injection, USP	7732-18-5	Balance	NE	NE	NE	NE	NE

NE - Not Established C - Ceiling Limit

3. HAZARDS IDENTIFICATION

Emergency Overview: Material is a clear, colorless, odorless liquid. Avoid contact with eyes, skin and clothing. Do not taste or swallow. Wash thoroughly after handling.

Symptoms of Overexposure by Route of Exposure:

Inhalation : This material is intended for injection under the supervision of physicians. Inhalation of significant amounts of the product is not anticipated to occur because of the small size of individual containers.

Contact with Skin or Eyes : Contact may cause irritation. Effects may include stinging, watering, and redness of the eyes and redness, itching, and a burning sensation on the skin.

Ingestion: Ingestion is not an anticipated route of occupational exposure. Symptoms similar to those identified under injection may occur.

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Injection : Local redness and pain are the primary symptoms of accidental injection in an occupational setting. Medical personnel are not anticipated to experience over-exposures to the therapeutic doses of this product. However, effects including headache, nausea, abdominal pain, facial flushing, changes in blood pressure and increased heart rate may occur. Severe allergic reactions including anaphylaxis have been reported rarely with injection. See package insert for other adverse reactions associated with therapeutic doses of this product.

Health Effects or Risks From Exposure (An explanation in lay terms) :

Acute: The primary health effects anticipated in an occupational setting include irritation of eyes and skin as well as redness and local swelling after accidental injection. In case of over-exposure by injection, effects such as headache, nausea, abdominal pain, facial flushing, changes in blood pressure and increased heart rate may occur.

Cancer: No long-term carcinogenicity studies were identified.

Chronic: None known.

Pre-Existing Medical Conditions: None known.

4. FIRST-AID MEASURES

Skin Exposure: Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.

Eye Exposure: If irritation or redness develops, move victim away from exposure and into fresh air. Flush eyes with clean water and seek medical attention.

Inhalation: If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention.

Ingestion : If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing

Victims of chemical exposure must be taken for medical attention. Take a copy of the MSDS to the physician or health professional with victim. Physicians should refer to Section 11 (Toxicological Information) as well as the Physicians Desk Reference for additional treatment information

5. FIRE-FIGHTING MEASURES

Flash Point : Non-flammable

Autoignition Temperature: Not applicable

Flammable Limits (in air by volume, %): Lower : Not applicable Upper: Not applicable

Fire Extinguishing Equipment: Use extinguishing agent suitable for type of surrounding fire.
Water Spray: OK Carbon Dioxide : OK Halon: OK
Foam: OK Dry Chemical : OK Other : Any "ABC" Class

Unusual Fire and Explosion Hazards: No unusual fire or explosion hazards are expected.

Explosion Sensitivity to

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Mechanical Impact : : Not sensitive.
Explosion Sensitivity to Static Discharge : : Not sensitive.

Special Fire Fighting Procedures: For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear bunker gear. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by DOT, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8). Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Move undamaged containers from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to fire with water, if it can be done with minimal risk.

NFPA HAZARD CLASS: **Health: 1 (Slight)**
Flammability: 0 (Least)
Reactivity: 0 (Least)

6. ACCIDENTAL RELEASE MEASURES

Spill and Leak Response: For small releases of this product, wear latex or nitrile gloves and safety glasses. Absorb spilled liquid, rinse area thoroughly with soap and water. For large or uncontrolled releases, stay away from spill. Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Wear appropriate protective equipment including respiratory protection as conditions warrant (see Section 8). Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways. Notify appropriate federal, state, and local agencies. Immediate cleanup of any spill is recommended.

7. HANDLING AND STORAGE

Work and Hygiene Practices: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Precautions should be taken during the following activities:

- Withdrawal of needles from drug vials.
- Drug transfers using syringes and needles or filter straws.
- Expulsion of air from drug-filled syringes.

Storage and Handling Practices: Employees must be trained to properly use the product. Ensure vials are properly labeled. Store only in approved containers. Protect from light. Keep away from any incompatible materials or conditions (see Section 10). Store refrigerated at temperatures between 2-8°C (36-46°F).

Protective Practices During Maintenance of Contaminated Equipment: When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials and other disposable items contaminated with this product should be disposed of properly.

**MATERIAL SAFETY DATA SHEET****8. EXPOSURE CONTROLS / PERSONAL PROTECTION****Ventilation and Engineering****Controls:****Respiratory Protection:**

Use with adequate ventilation. Follow standard medical product handling procedures. Not normally required for routine, medical administration of this product. A NIOSH certified air-purifying respirator with a type 95 filter may be used under conditions where airborne concentrations are expected to be excessive. Protection provided by air purifying respirators is limited (see manufacturer's respirator selection guide). Use a positive pressure air supplied respirator if there is potential for uncontrolled release, exposure levels are not known, or any other circumstances where air-purifying respirators may not provide adequate protection. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions warrant a respirator's use.

Eye Protection:

Approved eye protection to safeguard against potential eye contact, irritation or injury is recommended. Depending on conditions of use, a face shield may be necessary.

Hand Protection:

Use latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before and after using gloves.

Body Protection:

No special body protection required for routine, medical administration of this product. Wear lab coat, gown, or smock, as appropriate for procedure.

**Product Preparation Instructions
for Medical Personnel:**

Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.

9. PHYSICAL AND CHEMICAL PROPERTIES

Relative Vapor Density (air = 1) Not determined

Evaporation Rate (n-BuAc=1): Not applicable

Specific Gravity (water = 1): 1

Melting/Freezing Point: Not determined

Solubility in Water: Soluble

Boiling Point: Not determined

pH: 3.5 - 6.0

Vapor Pressure, mm Hg @ 25° C. Not determined

Odor Threshold: Odorless

Appearance and Color: Clear, colorless liquid

10. STABILITY AND REACTIVITY**Stability:**

Stable under normal conditions of storage and handling. Materials With Which Substance is Incompatible: This product is generally compatible with other common materials in a medical facility. Keep away from strong oxidizers.

Hazardous Polymerization:

Will not occur.

Hazardous Combustion Products:

Heat may cause product to decompose, destroying the product or producing toxic fumes.

**MATERIAL SAFETY DATA SHEET****11. TOXICOLOGICAL INFORMATION**

Toxicity Data : The following information is for Desmopressin Acetate, the active ingredient

IV LD50 (rabbit) > 50 µg/kg
IV LD50(rat) > 2 mg/kg

IV LD50(mouse) > 2 mg/kg
Sub Q (LD50(> 2 mg/kg

Suspected Cancer Agent :

No long-term animal studies were identified. It is not listed as carcinogenic by NTP, IARC or OSHA.

Sensitization to the Product:

Irritancy of Product: This product is expected to be mildly irritating to eyes and skin.
Severe allergic reactions including anaphylaxis have been reported rarely with injection.
Reproductive Toxicity Information : Listed below is information concerning the effects of Desmopressin Acetate on human and animal reproductive systems. This material is classified as a Pregnancy Category B (No evidence of risk).

Mutagenicity

No data identified.

**Embryotoxicity/
Teratogenicity/Reproductive
Toxicity:**

No data identified on potential to affect fertility. Not a teratogen in rats and rabbits.

**ACGIH Biological Exposure
Indices:**

Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product

12. ECOLOGICAL INFORMATION**Environmental Stability:
Effect of Materials on
Plants or Animals :**

This product will be relatively stable under ambient environmental conditions.

**Effect of Chemicals on
Aquatic Life:**

No specific information is available on the effect of Desmopressin Acetate on plants or animals in the environment.

No specific information is available on the effect of Desmopressin Acetate on plants or animals in the aquatic environment.

13. DISPOSAL CONSIDERATIONS**Preparing Wastes for Disposal:**

The material, if discarded as produced, is not a RCRA "listed" or "characteristic" hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.

U.S. EPA Waste Number:

None

**MATERIAL SAFETY DATA SHEET****14. TRANSPORT INFORMATION**

This Materials is not Hazardous as Defined by 49 CFR 172.101 by the U. S. Department of Transportation

Proper Shipping Name:	Not applicable
Hazard Class Number & Description:	Not applicable
UN Identification Number:	Not applicable
Packing Group:	Not applicable
DOT Label(s) Required:	Not applicable
North American Emergency Response Guidebook Number (1996):	Not applicable.
MARINE POLLUTANT:	No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B)
Transport Canada Transportation of Dangerous Goods Regulations:	Not applicable

15. REGULATORY INFORMATION**U.S. REGULATIONS**

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304 and 313 of Title II of the Superfund Amendments and Re-authorization Act.

U.S. SARA Threshold Planning

Quantity : Not applicable

U.S. CERCLA Reportable

Quantities (RQ) : Not applicable

U.S. TSCA Inventory Status: Desmopressin Acetate is a “drug” as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA.

California Safe Drinking Water & Toxic Enforcement Act

(Proposition 65): This product does NOT contain chemicals known to the State of California to cause cancer or reproductive effects – Other U.S. Federal Regulations : Based on this product’s use, the requirements of the OSHA Blood borne pathogen Standard (29 CFR 1910.1030) are applicable

16. OTHER INFORMATION

MSDS Version No : 1

Date : 05/02/2013

To the best of our knowledge, the information contained in this material safety data sheet is accurate. However, Sun Pharmaceutical Industries Ltd. does not assume any liability whatsoever for the accuracy or completeness of the information contained herein except for the product's use as intended. Final determination of the suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that these are the only hazards, which exist.

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