



MATERIAL SAFETY DATA SHEET

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product Name Desmopressin Acetate Nasal Solution, 10µg/0.1ml
Generic Name Desmopressin Acetate Nasal Solution, 10µg/0.1ml
Company Name Sun Pharmaceutical Industries Limited

2. COMPOSITION / INFORMATION ON INGREDIENTS

CAS#	CHEMICAL IDENTITY	EXPOSURE LIMITS				CARCINOGEN STATUS			
		ACGIH		OSHA		MANUF	IARC	NTP	OSHA
		TWA	STEL	STEL	PEL				
62288-83-9	DESMOPRESSIN ACETATE	NE	NE	NE	NE	1 ug/m3 8-hour	NR	NR	NR
8001-54-5	BENZALKONIUM CHLORIDE	NE	NE	NE	NE	NE	NR	NR	NR
7558-79-4	DISODIUM PHOSPHATE	NE	NE	NE	NE	NE	NR	NR	NR
7647-14-5	SODIUM CHLORIDE	NE	NE	NE	NE	NE	NR	NR	NR
77-92-9	CITRIC ACID	NE	NE	NE	NE	NE	NR	NR	NR
7732-18-5	WATER	NE	NE	NE	NE	NE	NR	NR	NR

NE = Not Established

NR = Not Reviewed

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

R36 Irritating to eyes. A full description of any adverse side effects can be found in section 11, the package insert or the Physician's Desk Reference.

Eye R36 Irritating to eyes

Skin Contact No data for determination of unusual hazard from skin contact are

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	available at this time
Skin Absorption	This material is soluble in water. Absorption through intact or abraded skin is possible and may cause systemic toxicity
Ingestion	Not harmful by definition based on LD50. A full description of adverse side effects can be found in section 11, the package insert or the Physician's Desk Reference
Inhalation	Not harmful by definition based on LD50. A full description of adverse side effects can be found in section 11, the package insert or the Physician's Desk Reference
Chronic Effects/ Carcinogenicity	Adverse potential reactions from long-term exposure are detailed in section 11, the package insert, the Physician's Desk Reference and/or the Martindale Extra Pharmacopoeia

4. FIRST-AID MEASURES

Eyes	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. (S26)
Skin	Wash with soap and water. Seek medical attention if symptoms appear
Ingestion	If swallowed inadvertently, seek medical advice immediately and show this container or label. (S46)
Inhalation	In case of accident or if you feel unwell seek medical advice immediately (show the label where possible). (S45)
Note to Physician	Please see Toxicology Information (Section 11). Additional details are available on the package insert or in the Physicians' Desk Reference

5. FIRE-FIGHTING MEASURES

General Hazards	CO, CO ₂ and oxides of nitrogen and sulfur may be generated in a fire
Fire Fighting Extinguishing Media	In case of fire use waterspray, foam or dry chemical. (S43)
Fire Fighting Instructions	In case of fire, use full firefighting turnout (bunker) gear and self-contained breathing apparatus (SCBA). Keep personnel upwind and away from fire. (S43)
Hazardous Combustion Products	CO, CO ₂ and oxides of nitrogen and sulfur may be generated in a fire



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6. ACCIDENTAL RELEASE MEASURES

Large Spill Contain spill. Absorb on suitable medium and deposit in container for disposal. Mop area with detergent and water.

Small Spill Absorb on paper towels. Deposit in suitable container for disposal. Broken glass requires additional caution. Wipe down area with detergent and water.

7. HANDLING AND STORAGE

Special Handling Protect package from physical damage. Wash thoroughly after handling.

Special Storage Store in a tightly closed container in a cool, dry location

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Eye Protection Clean-up, manufacturing and packaging operations require safety glasses or goggles.

Skin Protection Latex gloves or gloves of equal or greater protection are recommended for spill clean-up, manufacturing and packaging operations.

Respiratory Protection None normally required

Engineering Controls Clean-up, manufacturing and packaging operations should be designed so as to offer no significant exposure to the ingredients.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance Clear Liquid

Physical State Solution within dosing unit

Molecular Weight 1183.48

Molecular Formula C₄₈ H₆₈ N₁₄ O₁₄ S₂ . 3H₂O

10. STABILITY AND REACTIVITY

Incompatibility It is expected to be incompatible with strong oxidizers

Hazardous Decomposition Products Thermal decomposition products may include CO, CO₂ and oxides of nitrogen and sulfur

Hazardous Polymerization Hazardous polymerization has not been reported to occur under normal temperatures and pressures

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General Information No additional information.

11. TOXICOLOGICAL INFORMATION

Toxicology

ADVERSE EFFECTS AND PRECAUTIONS

Rare adverse effects with desmopressin include headache, nausea, and mild abdominal cramps; there may be pain and swelling at the site of injection. With large intravenous doses hypotension and facial flushing may occur; some patients may experience an increase in blood pressure. Occasionally there may be cerebral or coronary thrombosis. The antidiuretic action of desmopressin may lead to water intoxication and hyponatraemia. Nasal administration may cause local irritation, congestion and epistaxis. There are reports of seizures due to water intoxication following intranasal or intravenous desmopressin. Desmopressin is absorbed from the nasal mucosa with a bioavailability of 10 to 20%. Following oral administration it is largely destroyed in the gastro-intestinal tract and oral bioavailability is reportedly less than 0.5%, but sufficient is absorbed following high doses to produce therapeutic effects.

Precautions to be observed during the administration of desmopressin are similar to those for vasopressin.

12. ECOLOGICAL INFORMATION

Ecological Information No information for determination of unusual environmental fate or toxicity is available at this time .

13. DISPOSAL CONSIDERATIONS

Disposal Information Unused or used individual containers can be discarded in general refuse. Large quantities of unused material should be destroyed by incineration.

Waste Disposal Methods Waste must be disposed of in accordance with federal, state and local environmental regulations. Incineration is the preferred method.

14. TRANSPORT INFORMATION

DOT :

Proper Shipping Name

Not Regulated

Transportation of Hazardous Material See current DOT or IATA shipping regulations.



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15. REGULATORY INFORMATION

TSCA Inventory Status

This product is a pharmaceutical agent and as such is regulated by the United States Food and Drug Administration (FDA).

16. OTHER INFORMATION

Other Information The information contained herein is based upon data considered true and accurate. Sun Pharmaceutical Industries Limited makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

Revision Summary No revision.

