

MATERIAL SAFETY DATA SHEET

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Prepared by: Gary Wong
Manager EHS
Core No. 342

1. PRODUCT AND COMPANY INFORMATION

Product Name: Desmopressin Acetate Nasal Solution, 0.01%
Generic Name: Desmopressin Acetate Nasal Solution, 0.01%
NDC No. 24208-342-05 (5 ml)

Legal Category: Prescription only medicine, filled in 5 mL bottle with spray attachment and overpacked inside a cardboard carton.

Drug Composition: Synthetic peptide; antidiuretic hormone

BAUSCH & LOMB INCORPORATED

8500 Hidden River Parkway

Tampa, FL 33637

Information: (800) 323-0000 (M-F) 8am-5pm EST

Emergency: (800) 227-1427 24 hrs

2. COMPOSITION/INFORMATION ON INGREDIENTS

Description	CAS #	TLV (mg/m ³)	PEL (mg/m ³)	% Content
Desmopressin acetate	62357-86-2	NE	NE	0.01
Purified Water	7732-18-5	NE	NE	>1

Ingredients <1% - Chlorobutanol, Sodium chloride, hydrochloric acid

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Amber glass bottle with spray pump in cardboard box. Clear colorless solution with camphor like odor. Toxic by ingestion. Presents little or no hazard if spilled and no unusual hazard if involved in fire.

POTENTIAL HEALTH HAZARDS

Carcinogenicity: (NTP) No (IARC) No (OSHA) No

Eye: No data

Skin: No data

Ingestion: No data

Inhalation: As used in the nose, high dosages have produced nausea and headache. Nasal congestion, runny nose, skin flushing, and abdominal cramping are occasionally reported. Upper respiratory infections, sore throat, nosebleed, hypersensitivity may also occur in some individuals.

Chronic Effects: No data

Target Organs: Central nervous system.

Medical Conditions Aggravated by Long Term Exposure:

- Anaphylactic cross-reactions may occur.
 - Appropriate measures should be taken if this occurs.
- Hypersensitivity to any of the ingredients of the medication.

4. FIRST AID MEASURES

Remove from exposure and in the event of any untoward events, obtain appropriate medical attention. Persons developing serious hypersensitivity reactions must receive immediate medical attention.

Eyes: Rinse immediately with copious amounts of water for at least 20 minutes. Contact a physician.

Skin: Remove all contaminated clothing and wash skin with copious amounts of water for at least 20 minutes. Contact physician if skin becomes irritated.

Ingestion: Wash out mouth and drink plenty of water and bland fluids. The use of an emetic drug and/or gastric lavage is advisable. Do not give anything to an unconscious person. Contact physician.

Inhalation: Remove person to fresh air, and if breathing stops, use artificial respiration. Contact physician.

Note to Physicians: Additional details are available on the package insert or in the Physicians Desk Reference.

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash point: NE Method: NE

Flammable Limits: Lower flammable limit: N/A Upper flammable limit: N/A

Autoignition Temperature: None

Unusual Fire and Explosion Hazards: None.

Hazardous Products: None.

Extinguishing Media: Dry chemical, carbon dioxide, water spray or fog, and foam on surrounding materials.

Fire Fighting Instructions: As with all fires, evacuate personnel to safe area. Firefighters should wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool.

6. ACCIDENTAL RELEASE MEASURES

Large/Small Spills: Use personal protective equipment. Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste. Dispose of material according to Federal, State and Local regulations.

7. HANDLING AND STORAGE

Handling: This material should be handled and stored per label and other instructions to ensure product integrity. Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment.

Storage: Store product under refrigerated condition, at approximately 4°C (39°F). Do not Freeze. When traveling, closed bottles will maintain stability for three weeks if stored at controlled room temperature of 22 °C (72 °F). **KEEP THIS AND ALL OTHER DRUGS OUT OF THE REACH OF CHILDREN.**

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Engineering Controls: In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process, which will maintain the dust and vapor, levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical material and use current Material Safety Data Sheets.

Eye Protection: (29 CFR 1910.133) Recommend goggles or chemical safety glasses.

Skin Protection: Thick impermeable gloves and protective clothing.

Respiratory Protection: (29 CFR 1910.134) NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw materials.
Warning: Do not use air-purifying respirators in oxygen-depleted environments. No respiratory protection is required in the clinical or home environment.

Other: None

Ventilation: Recommended

Contaminated Equipment: Wash contaminated clothing separately. Wash contaminated equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.

9. CHEMICAL & PHYSICAL PROPERTIES

Appearance & Odor:	Clear, colorless solution; camphor like odor.		
Boiling Point:	Approx. 212 °F	Evaporation Rate:	NE
Specific Gravity:	As water	Vapor Density:	As water
Vapor Pressure:	As water	Viscosity:	NE
pH:	Approx 4	Solubility in water:	Soluble

10. STABILITY AND REACTIVITY

Chemical Stability: Product has shelf life that is temperature dependent.

Conditions to avoid: Extreme heat or cold.

Incompatibility: This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.

Hazardous Decomposition Products: No Data.

Hazardous Polymerization: Should not occur.

11. TOXICOLOGY

Summary of Risks: Toxicological information refers to raw materials product. Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see MSDS on chemical material

CAS #

62288-83-9

Desmopressin Acetate

Can cause hypersensitivity (anaphylactic) in some individuals. Intranasal desmopressin acetate at high dosage has infrequently produced a slight elevation in blood pressure, which disappears with a reduction in dose. Should be used with caution in patients with conditions associated with fluid and electrolyte imbalance, such as cystic fibrosis. Adverse reactions include transient headache and nausea.

12. ECOLOGICAL INFORMATION

Chemical Fate Information: Product administered to patients presents a negligible impact on the environment.

13. DISPOAL INFORMATION

Dispose of material according to Federal, State, and Local regulations. The method typically used is incineration.

EPA Designations: RCRA Hazardous Waste: Not Listed

SARA Title III: Not Listed

14. TRANSPORTATION INFORMATION

Transportation Data: Not classified as hazardous by DOT regulations.

15. REGULATORY INFORMATION

DOT Designations: Not classified as hazardous by DOT regulations.

EPA Designations: RCRA Hazardous Waste
(40 CFR 261.33) Not Listed

FDA Designations: Prescription only medication.
NDC No. 24208-342-05 (5 ml)

BAUSCH & LOMB INCORPORATED
MSDS: Desmopressin Acetate Nasal Solution, 0.01%

OSHA Designations: (29 CFR 1910.1000, Table Z)
Not Listed

SARA Title III: Not listed under Section 313 of Toxic Release Reporting.

CALIFORNIA PROPOSITION 65: Not Listed

16. OTHER INFORMATION

None

The information contained herein is furnished without warranty of any kind. The above information is believed to be correct but does not purport to be all-inclusive and should be used only as a guide. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers.

NE- Not Established
< - Less Than
> - Greater Than