



Safety Data Sheet

Section 1: Identification

Product identifier

- Product Name** • **Desmopressin Acetate Nasal Spray, 0.01%**
Product Code • AB34207; Core No. 342; NDC 24208--342-05

Relevant identified uses of the substance or mixture and uses advised against

- Recommended use** • Finished Pharmaceutical Product; Desmopressin acetate nasal solution as antidiuretic hormone replacement therapy.
Restrictions on use • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

- Manufacturer** • Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609
United States
bausch.com
Telephone (General) • 1-800-553-5340

Emergency telephone number

- Manufacturer** • 1-800-535-5053 - Infotrac

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 consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

- UN GHS** • Classification criteria not met

Label elements

UN GHS

Classification criteria not met

Precautionary statements

- Storage/Disposal** • Keep tightly closed and store in upright position.
Store product refrigerated at 2-8°C (36-46°F).
Use before expiration date marked on carton and/or container.

Other hazards

- UN GHS** • No data available.

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Chlorobutanol	CAS:57-15-8 EINECS:200-317-6	0.5%	UN GHS: NDA
Desmopressin Acetate Hydrate	CAS:16679-58-6 EINECS:240-726-7	0.01%	UN GHS: NDA
Sodium chloride	CAS:7647-14-5 EINECS:231-598-3	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5
Water	CAS:7732-18-5 EINECS:231-791-2	Balance	UN GHS: Not Classified

Hydrochloric Acid (CAS:7647-01-0, EINECS:231-595-7) may be added to adjust the pH.

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- IF INHALED: Call a POISON CENTER or doctor/physician if you feel unwell. Infrequently, high dosages of intranasal desmopressin acetate have produced transient headache and nausea. Nasal congestion, rhinitis and flushing have also been reported occasionally along with mild abdominal cramps. These symptoms disappeared with reduction in dosage. Nosebleed, sore throat, cough and upper respiratory infections have also been reported.

Skin

- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes. IF ON SKIN: Wash with plenty of soap and water.

Eye

- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Ingestion

- If swallowed, get medical help or contact a Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

Other information

- Additional details are provided on the product packaging and/or the product insert.

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media • Water spray, carbon dioxide, dry chemical powder, or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media • No data available.

Firefighting Procedures • As in any fire, wear self-contained breathing apparatus and full protective gear.

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards • None known.

Hazardous Combustion Products • None known.

Advice for firefighters

- No data available

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions • No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

Emergency Procedures • No emergency procedures are expected to be necessary when used in accordance with product literature.

Environmental precautions

- No data available on the environmental impact of this product.

Methods and material for containment and cleaning up

Containment/Clean-up Measures • Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal.

Section 7 - Handling and Storage

Precautions for safe handling

Handling • No special handling is required. Refer to Section 8. Use only in accordance with product literature. Use good safety and industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Storage • Keep tightly closed. Store between 2-8°C (36-46°F), to maintain product integrity. use before expiration date marked on carton and/or container.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines • Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure controls

Engineering Measures/Controls • No special controls are required under conditions of intended use. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment

Respiratory

- No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, a NIOSH-certified air-purifying respirator equipped with HEPA -organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits and when adequate oxygen is present. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

Eye/Face

- No special personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn.

Hands

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear rubber or nitrile gloves.

Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

Thermal hazards

- None known.

General Industrial Hygiene Considerations

- Wash thoroughly with soap and water after handling.

Environmental Exposure Controls

- No special controls are required under conditions of intended use. In the event of a bulk spill, prevent spilled material from entering storm sewers or drains, waterways, and contact with the soil.

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Color	Clear Colorless .
Odor	Camphor-like	Odor Threshold	Not relevant
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	3.5 to 6
Specific Gravity/Relative Density	= 1.008	Water Solubility	Not relevant
Viscosity	Not relevant		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	No data available	Volatiles (Wt.)	Not relevant
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Burning Time	Not relevant
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- Stable under normal temperatures and pressures.

Chemical stability

- Stable when stored refrigerated at 2-8C (36-46 F). Use before expiration date marked on carton and/or container. User may store at room temperature up to one month.

Possibility of hazardous reactions

- Will not occur.

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- None known.

Hazardous decomposition products

- None known.

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Desmopressin Acetate Hydrate (0.01%)	16679-58-6	Acute Toxicity: Intravenous-Human TDLo • 0.3 µg/kg 10 Minute(s); <i>Kidney, Ureter, and Bladder:Other changes in urine composition; Blood:Changes in cell count (unspecified)</i>
Chlorobutanol (0.5%)	57-15-8	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 150 mg/kg
Sodium chloride (< 1%)	7647-14-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 3000 mg/kg

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Classification criteria not met
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Classification criteria not met

Potential Health Effects

Inhalation

Acute (Immediate)

- Under normal conditions of use, no health effects are expected. Infrequently, high dosages of intranasal desmopressin acetate have produced transient headache and nausea. Nasal congestion, rhinitis and flushing have also been reported occasionally along with mild abdominal cramps. These symptoms disappeared with reduction in dosage. Nosebleed, sore throat, cough and upper respiratory infections have also been reported.

Chronic (Delayed)

- No data available.

Skin

Acute (Immediate)

- Not expected to cause skin irritation.

Chronic (Delayed)

- No data available

Eye

Acute (Immediate)

- Under normal conditions of use, no health effects are expected.

Chronic (Delayed)

- No data available.

Ingestion

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
 - No data available.

Section 12 - Ecological Information**Toxicity**

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available.

Bioaccumulative potential

- No data available.

Mobility in Soil

- No data available.

Other adverse effects**Section 13 - Disposal Considerations****Waste treatment methods**

- Product waste**
 - Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.
- Packaging waste**
 - Recycle

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	Not regulated	NDA	NDA	NDA
TDG	NDA	Not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not regulated	NDA	NDA	NDA

- Special precautions for user**
 - No data available

- Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
 - No data available

Section 15 - Regulatory Information**Safety, health and environmental regulations/legislation specific for the substance or mixture**

- SARA Hazard Classifications**
 - No data available

Section 16 - Other Information

Last Revision Date

- 05/May/2015

Preparation Date

- 05/May/2015

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