

SAFETY DATA SHEETS

This SDS packet was issued with item:

078944924

N/A

Safety Data Sheet

Section 1. Identification

Common/Trade name : **Desmopressin Nasal Spray Solution USP, 0.01%**

Recommended use : Pharmaceutical industry: Dosage form
Therapeutic category: Antidiuretic

This Safety Data Sheet has been provided to inform workers of the safety, health and environmental information associated with this product. It is to be used by people handling the material within the workplace only. It is not meant for patients taking the medication. Patients should consult with their physician, pharmacist or the information provided on the label or on the insert.

Recommended restrictions : No other uses are advised.

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Section 2. Hazards Identification

Classification of the substance or mixture : As per 29 CFR 1910.1200 (b)(6) and according to Article 1, item 5 a) of CLP Regulation (EC) 1272/2008, medicinal products (drugs) when it is in the solid, final form for direct administration to the patient or are packaged by the manufacturer for sale to consumers in a retail establishment are exempt from the requirements of classification, labels and SDS's.

GHS label elements : Exempt from requirements.

Hazards not otherwise classified : Exempt from requirements.

Section 3. Composition/Information on Ingredients

| Name | CAS # | % (w/w) |
|-------------------------------------|------------|---------|
| Desmopressin acetate | 62357-86-2 | 0.01 |
| Benzalkonium chloride | 8001-54-5 | <1 |
| Sodium phosphate, dibasic 7-hydrate | 7782-85-6 | <1 |
| Sodium chloride | 7647-14-5 | <1 |
| Citric acid | 77-92-9 | <1 |

Specific chemical identity and/or percentage of composition has been withheld as a trade secret.

Chemical name : Not applicable.

Synonyms : Not available.

Chemical family : Cyclic polypeptide

Molecular weight : Not applicable.

Chemical formula : Not applicable.

Section 4. First Aid Measures

- Eye contact** : Flush with copious quantities of water. If irritation persists, obtain medical advice.
- Skin contact** : Flush with copious amounts of water. Seek medical attention if irritation persist.
- Inhalation** : Remove from exposure. Persons developing serious hypersensitivity reactions must receive immediate medical attention. If not breathing give artificial respiration. If breathing is difficult give oxygen.
- Ingestion** : Never give anything by mouth if victim is losing consciousness, or is unconscious or convulsing. Rinse mouth thoroughly with water. If breathing is difficult, give oxygen. If breathing has stopped, trained personnel should begin artificial respiration, or if the heart has stopped, cardiopulmonary resuscitation (CPR) immediately. Seek medical attention.
- Potential acute and delayed health effects** : Refer to Sec. 11

Section 5. Fire Fighting Measures

- Specific hazard arising from the chemical** : During fire, gases hazardous to health may be formed.
- Suitable extinguishing media and special protective equipment for firefighters** : Extinguisher media: Use extinguishing media suitable for surrounding materials.
Special fire fighting procedures: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

- Methods and materials for containment and cleaning up** : Assess hazard levels. Contain and clean up spillage and place into an appropriate labeled waste disposal container. Avoid generating dust or aerosols. Wash spill surface using appropriate cleaning solutions. Should clothing be contaminated, wash before reuse.
- Protective equipment and personal precautions** : Keep unnecessary personnel away. Wear appropriate personal protective equipment.

Section 7. Handling and Storage

- Precautions for safe handling** : Avoid contact with eyes.
- Conditions for safe storage** : Store at 25°C (77°F) [see USP Controlled Room Temperature]; excursions permitted to 15-30°C (59-86°F). Store bottles in upright position.

Section 8. Exposure Controls/Personal Protection

- Engineering Controls** : General room ventilation. Local exhaust ventilation and/or process enclosures where applicable. Fume hoods where available. Additional respiratory protection is not required when working in a fume hood.

| | |
|-------------------------------------|--|
| Personal Protection | : Skin: Lab coat |
| | Respiratory: Under normal work conditions, the use of respiratory protective equipment is not expected to be required. If the physical state of the finished product is altered by crushing, grinding or breakage or for spill cleaning, an approved NIOSH respirator may be required. |
| | Hand: Nitrile gloves |
| | Eye: Safety glasses |
| Occupational exposure limits | : Not established. |

Section 9. Physical and Chemical Properties

| | | | |
|--|---------------------|----------------------------------|-------------------------|
| Physical state and appearance | : Solution | | |
| pH | : Not available. | Odor | : Not available. |
| Melting point/ Freezing point | : Not available. | Odor threshold | : Not available. |
| Boiling point | : Not available. | Conditions of instability | : No additional remark. |
| Volatility | : Not available. | Decomposition temperature | : Not available. |
| Specific gravity | : Not available. | Partition Coefficient: | : Not available. |
| Evaporation rate | : Not available. | Viscosity | : Not available. |
| Vapor density | : Not available. | Flash points | : Not applicable. |
| Relative density | : Not available. | Flammable limits | : Not applicable. |
| Vapor pressure | : Not available. | Autoignition temperature | : Not applicable. |
| Flammability | : Not flammable. | | |
| Solubility | : Soluble in water. | | |

Section 10. Stability and Reactivity

| | |
|--|--|
| Reactivity | : Not available. |
| Chemical Stability | : The product is stable. |
| Possibility of hazardous reactions | : Not available. |
| Hazardous decomp. products | : When heated to decomposition material emits toxic fumes. |
| Incompatible materials/ Conditions to avoid | : Protect from heat. |

Section 11. Toxicological Information

Information on the likely routes of exposure : Inhalation. Eye contact.

Toxicity data : Desmopressin acetate:
RTECS#: YW9000000
LDLo: 891 ng/kg/1D-I (intravenous -man)
LD50: >2 mg/kg (intravenous-rat)

Delayed and immediate effects and also chronic effects from short and long term exposure : Specific target organ toxicity - repeated exposure: May cause damage to organs (kidney) through prolonged or repeated exposure.

Carcinogenicity: Not listed as carcinogen by IARC, NTP, ACGIH, or OSHA.

Reproductive Toxicity: No information available.

Teratogenicity: Category B: Fertility studies have not been done. Teratology studies in rats and rabbits at doses from 0.05 to 10 µg/kg/day (approximately 0.1 times the maximum systemic human exposure in rats and up to 38 times the maximum systemic human exposure in rabbits based on surface area, mg/m²) revealed no harm to the fetus due to DDAVP (desmopressin acetate). There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Mutagenicity: No information available.

Remark

Not available.

Symptoms related to the physical, chemical and toxicological characteristics : Adverse effects: 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.

Section 12. Ecological Information

Ecotoxicity : Not available.

Persistence and degradability : Not available.

Bioaccumulative potential : Not available.

Mobility in soil : Not available.

Other adverse effects : Not available.

Section 13. Disposal Considerations

Waste Disposal : Follow all appropriate safe work procedures and local regulations for disposal. Use only licensed disposal and waste hauling companies.

Section 14. Transport information

| Regulatory information | UN number | Proper shipping name | Class | Packing group | Additional information |
|--------------------------|-----------|----------------------|----------------|---------------|------------------------|
| TDG- road Canada/U.S. | | | Not regulated. | | |
| ICAO/IATA | | | Not regulated. | | |
| IMDG Class | | | Not regulated. | | |

Section 15. Regulatory Information

Canada Regulations : No additional remark.

Not on the DSL list.

Other Regulations : Not available.

Section 16. Other Information

References : RTECS Database
RxList Monographs
Apotex Product Monograph
U.S. Pharmacopeia

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