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Section 1 - Identification


- (a) **Product Identifier:** Desmopressin Acetate Injection
- (b) **Product Code:** 70860-454
- Common/Trade Name:** Desmopressin Acetate Injection
- Chemical Name:** 1-(3-mercaptopropionic acid)-8-D-arginine vasopressin monoacetate (salt)
- Chemical Family:** Synthetic Hormone
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

Section 2 - Hazards Identification

Overview Desmopressin Acetate Injection is a solution containing desmopressin acetate, an antidiuretic hormone used to control polydipsia, polyurea and dehydration in patients with diabetes insipidus. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract and a potent drug. Based on clinical use, potential target organs include the cardiovascular system and kidneys.

- (a) **Classification of substance or mixture:** Health Hazard : Not Classified
Physical Hazard : Not Classified

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	
Signal Word:	N/A
Hazard Statement:	N/A
Symbols:	N/A

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Precautionary Statements:	<p>Prevention: Do not breathe vapor or spray. Wash hands thoroughly after handling</p> <p>Response: Get medical attention if you feel unwell.</p> <p>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 attention.</p>
Other Hazards	N/A

(d) Unknown Acute Toxicity N/A


Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
1-(3-mercaptopropionic acid)-8-D-arginine vasopressin monoacetate salt	Desmopressin Acetate, USP	4 mcg/ml	62288-83-9	N/A
Chlorobutanol	Chlorobutanol	5 mg/mL	57-15-8	N/A
Sodium Chloride	Sodium chloride	9 mg/mL	7647-14-5	N/A
Hydrochloric Acid	Hydrochloric Acid	q.s. to adjust pH	7647-01-0	N/A

q.s. – Quantity Sufficient

Section 4 – First Aid Measures

Eye Exposure:	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Skin Exposure:	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Ingestion:	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary

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Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Notes to Physician: See patient package insert in shipping carton for complete information

Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.
- (b) **Hazardous Combustion Products:** None anticipated for this aqueous product
- (c) **Special Protective Equipment / Precautions:** No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus.

Section 6 - Accidental Release Measures

Spill: Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

Release to Air: N/A

Release to Water: N/A


Section 7 - Handling and Storage

General Handling: No special handling required for hazard control under conditions of normal product use.

Storage Conditions: Store refrigerated between 2° and 8°C (36° and 46°F).

Section 8 - Exposure Controls / Personal Protection

(a) **Exposure Guidelines**

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Compound	Issuer	Type	Exposure Limit
Desmopressin	OSHA	PEL	Not Established
Acetate	ACGIH	TLV	Not Established
Trihydrate	AIHA	WEEL	Not Established


OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
AIHA WEEL: Workplace Environmental Exposure Level

(b) Engineering Controls

Engineering controls are normally not needed during the normal use of this product.

(c) Individual Protection Measures


Respiratory Protection:	Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.
Eye Protection:	Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.
Skin Protection:	If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.
Other Protective Equipment:	Not established.
Additional Exposure Precautions:	Not established.

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(a)	Appearance	Clear to slightly opalescent, colorless to yellow, sterile solution.
(b)	Odor	Not available
(c)	Odor Threshold	Not available
(d)	pH	4.0
(e)	Melting Point:	Not available
(f)	Initial Boiling Point:	Not available
(g)	Flash Point	Not available
(h)	Evaporation Rate:	Not available
(i)	Flammability	Not available
(j)	Upper Lower Flammability or Explosion Limits	Not available
(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	Not available
(n)	Solubility(ies)	Not applicable
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

(a)	Reactivity	Not determined
(b)	Chemical Stability	Stable under standard use and storage conditions.
(c)	Possibility of Hazardous Reactions	Not determined.
(d)	Conditions to Avoid	Strong acids and bases, excessive heat.
(e)	Incompatible Materials	Not determined.
(f)	Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (CO _x), nitrogen oxides (NO _x), and sulfur oxides (SO _x).

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Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	<p>Inhalation, eye/skin contact or ingestion.</p> <p>Information on the absorption of this product via skin contact is not available. The active ingredient is bioavailable via the nasal route. Avoid liquid aerosol generation and skin contact.</p>
(b)	Symptoms related to the physical, chemical and toxicological characteristics	<p>None anticipated from normal handling of this product. In clinical use, adverse effects may include headache, nausea, and mild abdominal cramps; pain and swelling at the site of injection have been reported. Following large intravenous doses, hypotension, with tachycardia and facial flushing, may occur; some patients may experience an increase in blood pressure. Infrequently, there may be cerebral or coronary thrombosis. Hypersensitivity reactions have also occurred. The antidiuretic action of desmopressin can produce water intoxication and hyponatraemia, occasionally leading to convulsions. Nasal doses may cause local irritation, congestion, and epistaxis. Nosebleeds have also been reported.</p>
(c)	Delayed and immediate effects and chronic effects from short and long-term exposure	<p>None anticipated from normal handling of this product.</p>

(d) Acute Toxicity: Not determined for the product formulation. Information for the active ingredient is as follows:

Component	Type	Route	Species	Dosage
Desmopressin Acetate	LD ₅₀	Intravenous	Rat, Mouse	>2 mg/kg
	LD ₅₀	Intravenous	Rabbit	>50 mg/kg

Reproductive Effects: None anticipated from normal handling of this product. Fertility and general reproductive performance in rats were unaffected by subcutaneous doses of bivalirudin up to 150 mg/kg/day. Teratogenicity studies have been performed in rats at subcutaneous doses up to 150 mg/kg/day and rabbits at subcutaneous doses up to 150 mg/kg/day. No evidence of impaired fertility or harm to the fetus attributable to bivalirudin was noted in these studies.

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(e) Hazardous Chemical Listings

NTP: Not Listed **IARC:** Not Listed **OSHA:** Not Listed

Section 12 - Ecological Information

(a)	Ecotoxicity	Not determined for product.
(b)	Persistence and degradability	Not determined for product.
(c)	Bioaccumulative potential	Not determined for product
(d)	Mobility in soil	Not determined for product
(e)	Other Adverse Effects	Not determined for product

Section 13 - Disposal Considerations


Waste Disposal: All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal: Dispose of container and unused contents in accordance with federal, state and local regulations.

Section 14 - Transport Information

DOT: Not regulated as a dangerous good.
IATA: Not regulated as a dangerous good.
IMDG: Not regulated as a dangerous good.

(a)	UN Number	N/A
(b)	UN Proper Shipping Name	N/A
(c)	Transport Hazard Class(es)	N/A
(d)	Packing Group	N/A
(e)	Environmental Hazards	N/A
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	N/A
(g)	Special Precautions	N/A

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Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

- TSCA – Not regulated
- CERCLA - Not on this list
- SARA 302 - Not on this list
- SARA 311/312: Not on this list
- SARA 313 - Not on this list
- OSHA – Not on this list

Section 16 - Other Information


As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Athenex Pharmaceutical Division
 10 N. Martingale Road, Suite 230
 Schaumburg, IL 60173
 847-886-9515

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances

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ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
RTU	Ready to Use
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System