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Section 1 - Identification


- (a) **Product Identifier:** Arsenic Trioxide Injection
- (b) **Product Code:** 70860-217
Common/Trade Name: Arsenic Trioxide Injection
Chemical Name: As₂O₃
Chemical Family: Arsenical
- (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

This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

- (a) **Classification of substance or mixture:** Carcinogenicity, Category 1

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	
Signal Word:	DANGER!
Hazard Statement:	H350 May cause cancer
Symbols:	

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Precautionary Statements:	P201 Obtain special instruction before use P202 Do not handle until all safety precautions have been read and understood. P280 Wear protective gloves/protective clothing/eye protection/face protection P308 + P313 IF exposed or concerned: Get medical advice/attention. P405 Store locked up P501 Dispense contents/container in accordance with local/regional/national/ international regulations
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
Arsenic trioxide	Arsenic trioxide	1.0 mg/mL	1327-53-3	N/A
Water for Injection	Water for Injection	q.s. to 1 mL	7732-18-5	N/A
Sodium Hydroxide	Sodium Hydroxide	1.2 mg/mL	1310-73-2	N/A
Sodium Hydroxide	Sodium Hydroxide	q.s.*	1310-73-2	N/A
Hydrochloric Acid	Hydrochloric Acid	q.s.*	7647-01-0	N/A
Nitrogen	Nitrogen	q.s.	7727-37-9	N/A

* q.s. – Quantity Sufficient added for pH adjustment approximately to achieve a target of pH of 8.0.

Section 4 – First Aid Measures

- Eye Exposure:** Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
- Skin Exposure:** Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.

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Ingestion: If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

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

Section 5 – Fire-fighting Measures


- (a) **Extinguishing Media** Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- (b) **Hazardous Combustion Products:** Thermal decomposition can lead to release of irritating gases and vapors. Combustible material.
- (c) **Special Protective Equipment / Precautions:** As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
- (d) **Fire Fighting Instructions** Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.

Section 6 - Accidental Release Measures

Spill: Evacuate area and keep unnecessary and unprotected personnel from entering the spill area.
Avoid dust/aerosol formation.
Avoid personal contact and breathing dust, vapors, mist, or gas.
Use proper personal protective equipment as listed in Section 8.

Release to Air: Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

Release to Water: Avoid runoff into storm sewers, ditches, and waterways.

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Section 7 - Handling and Storage

General Handling: When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Wash thoroughly after handling.

Use with adequate ventilation. Use only in accordance with directions.

Avoid contact with eyes and skin. Avoid inhaling dust, vapor or mist.

Storage Conditions: Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). [See USP Controlled Room Temperature.] Do not freeze.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Guidelines

Compound	Issuer	Type	Exposure Limit
Hydrochloric Acid	OSHA	PEL-STEL	5 ppm Ceiling/Peak
	ACGIH	TLV-STEL	2 ppm (ceiling)
	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

STEL: Short Term Exposure Limit


(b) Engineering Controls

General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose.

Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.

(c) Individual Protection Measures


Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances.
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Eye Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection:	Protective laboratory coat, apron, or disposable garment recommended. Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Other Protective Equipment:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.
Additional Exposure Precautions:	<i>General Hygiene Considerations:</i> Wash thoroughly after handling. Do not eat, drink, smoke or apply cosmetics while handling the product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Work should be performed in a designated area for working with hazardous drugs. Contaminated waste must be properly handled. Work areas must be regularly decontaminated.

Section 9 - Physical and Chemical Properties

(a)	Appearance	Colorless, aqueous solution.
(b)	Odor	Not available
(c)	Odor Threshold	Not available
(d)	pH	8.0
(e)	Melting Point:	Not available
(f)	Initial Boiling Point:	100° C
(g)	Flash Point	Not available
(h)	Evaporation Rate:	Similar to water
(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

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(r)	Viscosity	Not available
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Section 10 - Stability and Reactivity

(a)	Reactivity	Not determined
(b)	Chemical Stability	Stable under normal temperatures and pressures.
(c)	Possibility of Hazardous Reactions	Not determined.
(d)	Conditions to Avoid	Avoid direct sunlight, conditions that might generate heat, and sources of ignition. Avoid contact with incompatible materials. Do not expose to extreme temperatures.
(e)	Incompatible Materials	Avoid storage strong acids, strong bases, products incompatible with water.
(f)	Hazardous Decomposition Products	May emit fumes under fire conditions.


Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Inhalation, eye/skin contact or ingestion. 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.
(b)	Symptoms related to the physical, chemical and toxicological characteristics	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.
(c)	Delayed and immediate effects and chronic effects from short and long-term exposure	None anticipated from normal handling of this product.

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

Component	Type	Route	Species	Dosage
Arsenic trioxide	LD ₅₀ LD ₅₀	Oral	Rat	10 mg/kg
Sodium hydroxide	LDLo	Oral	Rabbit	500 mg/kg
Hydrochloric acid	T	Eye	Rabbit	5mg/30S (RTECS)
Hydrochloric acid	LC ₅₀	Inhalation	Rat	3124 ppm/1H [Sense Organs and Special Senses (Olfaction) - effect, not Otherwise specified Sense Organs and Special Senses (Eye) - Iritis]
Hydrochloric acid		Skin	Human	Human Standard Draize test.: 4 %/24H (RTECS)
Hydrochloric acid	LC ₅₀	Inhalation	Mouse	1108 ppm/1H [Sense Organs and Special Senses (Eye) - effect, not Otherwise specified Lungs, Thorax, or Respiration - Respiratory stimulation Skin and Appendages - Dermatitis, other (After systemic exposure)]
Hydrochloric acid	LC ₅₀	Inhalation	Rat	45000 mg/m 3/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Hydrochloric acid	LC ₅₀	Inhalation	Rat	8300 mg/m 3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Hydrochloric acid	LC ₅₀	Inhalation	Mouse	8300 mg/m 3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Hydrochloric acid	LC ₅₀	Inhalation		0.1 gm/m 3 [Details of toxic effects not reported other than lethal dose value]
Hydrochloric acid	LC ₅₀	Inhalation	Rat	60938 mg/m 3/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Hydrochloric acid	LC ₅₀	Inhalation	Mouse	20487 mg/m 3/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Hydrochloric acid	LC ₅₀	Inhalation	Rat	7004 mg/m 3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema]

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Hydrochloric acid	LC ₅₀	Inhalation	Mouse	3940 mg/m 3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Hydrochloric acid	LC ₅₀	Inhalation	Rat	3700 ppm/30M [Details of toxic effects not reported other than lethal dose value]
Hydrochloric acid	LC ₅₀	Inhalation	Mouse	2644 ppm/30M [Details of toxic effects not reported other than lethal dose value] (RTECS)
Hydrochloric acid	LD ₅₀	Oral	Rabbit	900 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

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

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(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 for Arsenic Trioxide

- TSCA – Not on this list
- CERCLA - Listed
- SARA 302 – Listed
- SARA 304 – Listed
- 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

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DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
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