
	Zoledronic Acid Injection		Safety Data Sheet (SDS)	
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Section 1 - Identification

- (a) **Product Identifier:** Zoledronic Acid Injection
- (b) **Product Code:** 70860-210
- Common/Trade Name:** Zometa
- Chemical Name:** (1-Hydroxy-2-imidazol-1-phosphonomethyl) phosphonic acid monohydrate
- Chemical Family:** Bisphosphonic Acid/Bisphosphonate
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial, Infusion Bag
- (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

- (a) **GHS Classification of substance or mixture:** Toxic to Reproduction, Category 2
- NFPA Rating**
 Health Hazard: 1
 Fire Hazard: 0
 Reactivity Hazard: 0

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	
GHS Signal Word:	Warning
GHS Hazard Statement:	H361: Suspected of damaging fertility or the unborn child.
GHS Symbols:	

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GHS Precautionary Statements:	<p>P201: Obtain special instructions before use.</p> <p>P202: Do not handle until all safety precautions have been read and understood.</p> <p>P308 + P313: IF exposed or concerned: Get medical advice/attention.</p> <p>P405: Store locked up.</p> <p>P501: Dispose of contents/container in accordance with local/provincial/federal regulations.</p>
Other Hazards	None classifiable

(d) **Unknown Acute Toxicity** N/A

Section 3 – Composition / Information on Ingredients

4 mg/100 mL Vial

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
(1-Hydroxy-2-imidazol-1-phosphonomethyl) phosphonic acid monohydrate	Zoledronic Acid	4.0* mg/100 mL	118072-93-8	N/A
Sodium Citrate Dihydrate USP	Sodium Citrate	24.0 mg/100 mL	6132-04-3	N/A
Mannitol USP	Mannitol	5100.0 mg/100 mL	69-65-8	N/A
Water for Injection USP	Water for Injection	q.s. to 100 mL	7732-18-5	N/A
Nitrogen NF	Nitrogen	A.R	7727-37-9	N/A

*4.264 mg of Zoledronic Acid Monohydrate is equivalent to 4.0 mg of Zoledronic Acid and Assay correction required on as-is basis.


q.s. – Quantity Sufficient

A.R. – As Required

Section 4 – First Aid Measures

Eye Exposure:

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

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- Skin Exposure:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Injection:** See patient package insert in shipping carton for complete information.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.
- Notes to Physician:** See patient package insert in shipping carton for complete information.

Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** Use carbon dioxide, dry chemical, or water spray.
- (b) **Hazardous Combustion Products:** Fine particles (such as dust and mists) may fuel fires/explosions.
- (c) **Special Protective Equipment / Precautions:** During all fire-fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Section 6 - Accidental Release Measures

- Spill:** Contain the source of the spill if it is safe to do so. Collect spilled material in a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly. Place waste in an appropriately labeled, sealed container for disposal.
- Large spills – non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
- Release to Air:** Care should be taken to avoid environmental release.
- Release to Water:** Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

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Section 7 - Handling and Storage

General Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Use appropriate personal protective equipment (PPE) while handling (see section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided.

Storage Conditions: Store at 25°C (77°F), excursions permitted between 15° to 30°C (59° to 86°F).

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Zoledronic Acid	OSHA ACGIH	PEL	NE
		TLV	NE
		STEL	NE
Mannitol	OSHA ACGIH	PEL	NE
		TLV	NE
		STEL	NE
Sodium Citrate	OSHA ACGIH	PEL	NE
		TLV	NE
		STEL	NE

Notes:

OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit


ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.

(b) Engineering Controls

Ventilation: Engineering controls should be used as a primary means of control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits of >1ug/m3 to <10ug/m3

(c) Individual Protection Measures

Respiratory Protection:	If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.
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Eye Protection:	Wear safety glasses or goggles if eye contact is possible.
Skin Protection:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Other Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Additional Exposure Precautions:	Not applicable

Section 9 - Physical and Chemical Properties

(a)	Appearance	clear, colorless solution
(b)	Odor	Not available
(c)	Odor Threshold	Not available
(d)	pH	6.0 to 7.0
(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)	Soluble in water
(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 available
(b)	Chemical Stability	Stable under standard use and storage conditions.
(c)	Possibility of Hazardous Reactions	Hazardous polymerization will not occur

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(d) Conditions to Avoid	No data available
(e) Incompatible Materials	As a precautionary measure, keep away from strong oxidizers
(f) Hazardous Decomposition Products	Carbon monoxide, carbon dioxide, formed under fire conditions

Section 11 - Toxicological Information

(a) Likely Routes of Exposure	Skin and eye contact, ingestion, inhalation
(b) Symptoms related to the physical, chemical and toxicological characteristics	Common adverse effects include nausea, vomiting, gastrointestinal irritation, fatigue, decreased red blood cell count (anemia), constipation, fever, shortness of breath (dyspnea) and bone pain.
(c) Delayed and immediate effects and chronic effects from short and long term exposure	May damage fertility or unborn child.

(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Zoledronic Acid	Minimum Lethal Dose	Intravenous	Mouse	>10mg/Kg
	Minimum Lethal Dose	Intravenous	Rat	>0.6 mg/Kg
Mannitol	LD ₅₀	Oral	Rat	13500 mg/kg
	LD ₅₀	Oral	Mouse	22.00g/kg


(e) Hazardous Chemical Listings

NTP: Not Listed

IARC: Not Listed

OSHA: Not Listed

Section 12 - Ecological Information

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(a) Ecotoxicity	Data is for drug substance and not finished product. <u>Daphnia Magna (water flea) Toxicity</u> EC50 after 48 hrs: > 18 mg/L <u>Algae (<i>selenastrum capricornutum</i>) Toxicity</u> EbC50 (72 hrs): 5.1 mg/L ErC50 (72 hrs): 15 mg/L NoEC (72 hrs): 2.2 mg/L <u>Bacterial Respiration (Activated Sludge) Inhibition:</u> EC50: 100 mg/L
(b) Persistence and degradability	Data is for drug substance and not finished product. Degradation is 1-3% over a duration of 28 days
(c) Bioaccumulative potential	No applicable ecological information found.
(d) Mobility in soil	No applicable ecological information found.
(e) Other Adverse Effects	No applicable ecological information found.


Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and 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
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