


AVENACY	Document Type: Safety Data Sheet	Zoledronic Acid Injection		
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Section 1 - Identification

- (a) **Product Identifier:** Zoledronic Acid
- (b) **Product Code:** 83634-801
- Common/Trade Name:** Zometa®
- Chemical Name:** (1-Hydroxy-2-imidazol-1-yl-phosphonoethyl) phosphonic acid monohydrate
- Chemical Family:** Bisphosphonate
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Avenacy 10 N. Martingale Road, Suite 225, Schaumburg, IL 60173, 847-773-4901
- (e) **Emergency Telephone:** 855-283-6229

Section 2 - Hazards Identification

- (a) **GHS Classification of substance or mixture:** Reproductive toxicity; Category 2

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
GHS Signal Word:	Warning
GHS Hazard Statement:	H361: Suspected of damaging fertility or the unborn child
GHS Symbols:	
GHS Precautionary Statements:	P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood P281: Use personal protective equipment as required P308 and P313: IF exposed or concerned: Get medical attention/advice P501: Dispose of contents/container in accordance with local/regional/national/international regulations
Other Hazards	An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

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-Hydroxy-2-imidazol-1-yl-phosphonoethyl) phosphonic acid monohydrate	Zoledronic Acid	4 mg/5 mL	118072-93-8	N/A
Sodium Citrate	Sodium Citrate	24 mg/5 mL	6132-04-3	NA
Mannitol	Mannitol	220 mg/5 mL	69-65-8	NA

Section 4 – First Aid Measures

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

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.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.


Injection: See patient package insert in shipping carton for complete information.

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:** Formation of toxic gases is possible during heating or fire.

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- (c) **Special Protective Equipment / Precautions:** During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Section 6 - Accidental Release Measures

- Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
- Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Clean spill area thoroughly.
- Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
- Additional Considerations for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.


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 as directed by product packaging.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

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

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(b) Engineering Controls


Engineering controls should be used as the primary means to control exposure. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits of $>1\mu\text{g}/\text{m}^3$ to $<10\mu\text{g}/\text{m}^3$.

(c) Individual Protection Measures

Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
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.
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.

Section 9 - Physical and Chemical Properties

(a)	Appearance	Clear, colorless solution
(b)	Odor	Not available
(c)	Odor Threshold	Not available
(d)	pH	5.7 to 6.7
(e)	Melting Point:	Not determined
(f)	Initial Boiling Point:	Not determined
(g)	Flash Point (Liquid) (°C)	Not determined
(h)	Evaporation Rate:	Not determined
(i)	Flammability	Not determined
(j)	Upper Lower Flammability or Explosion Limits	Not determined
(k)	Vapor Pressure (kPa):	Not determined
(l)	Vapor Density:	Not determined
(m)	Relative Density	Not determined
(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

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Section 12 - Ecological Information

The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

(a)	Ecotoxicity	N/A
(b)	Persistence and degradability	N/A
(c)	Bioaccumulative potential	N/A
(d)	Mobility in soil	N/A
(e)	Other Adverse Effects	N/A

Section 13 - Disposal Considerations

Waste Disposal: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and waste water.

Section 14 - Transport Information

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15 - Regulatory Information


Below is selected regulatory information chosen primarily for possible Avenacy 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.

Zoledronic Acid

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons	Schedule 4
EU EINECS/ELINCS List	Not Listed

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

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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:

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Schaumburg, IL 60173
847-773-4901

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
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

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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