Section 1 - Chemical Product and Company

Distributor:
Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600

Emergency Telephone: 866-625-1618

Product Identifier: Zoledronic Acid
Product Code: 25021-801, 25021-826
Common/Trade Name: Zometa®
Chemical Name: (1-Hydroxy-2-imidazol-l-yl-phosphonoethyl) phosphonic acid monohydrate
Chemical Family: Bisphosphonate
Product Use: Hypercalcemia of Malignancy, tumor induced hypercalcemia
Product Type: Regulated Prescription Drug
Container Information: Vial and Bag

Section 2 - Composition / Information on Ingredients

Ingredient	Approx. Weight %		CAS. No.
	4mg/5mLVial	4mg/100mL Bag	
Zoledronic Acid	0.08	0.004	118072-93-8
Sodium Chloride	--	0.89	7647-14-5
Mannitol	4.19	0.22	69-65-8
Sodium Citrate	0.46	pH Adj.	6132-04-3
Water for Injection	95.27	98.89	7732-18-5

Section 3 - Hazards Identification

Primary Physical and Health Hazards: May damage fertility or unborn child.

Routes of Entry: Skin and eye contact, ingestion, inhalation

Signs & Symptoms of Exposure: Common adverse effects include nausea, vomiting, gastrointestinal irritation, fatigue, decreased red blood cell count (anemia), constipation, fever, shortness of breath (dyspnea) and bone pain.

Chemical Listed as Carcinogen: **NTP:** No **IARC:** No **OSHA:** No

Medical Conditions Generally Aggravated by Exposure: Pregnancy; pre-existing renal insufficiency; pre-existing hypocalcemia; known hypersensitivity to zoledronic acid or any of the excipients.

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. See, 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

Flash Point: Not established

Auto-ignition Temperature: Not established

Flammable Limits in Air: Lower %: Not established
Upper %: Not established

Flammable Limits: Not established

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray

Special Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Unusual Fire/Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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.

Section 7 - Handling and Storage

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

Waste Disposal Method: Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F). [See Controlled Room Temperature]. Follow instructions provided in packaging.

Section 8 - Exposure Controls / Personal Protection

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.

Eye Protection: Wear safety glasses or goggles if eye contact is possible.

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/m^3 to <10ug/m^3

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

Exposure Limits

Compound	Issuer	Type	OEL
Zoledronic Acid	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Mannitol	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Citric Acid	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

Section 9 - Physical and Chemical Properties

Physical State:	Sterile Solution	**Specific Gravity:**	Not available
Appearance and Odor:	Clear, colorless	**Evaporation Rate:**	Not available
Boiling Point:	Not available	**Melting Point:**	Not available
Vapor Pressure:	Not available	**Solubility in Water:**	Highly Soluble
Vapor Density:	Not available	**pH:**	5.7-6.7 (Vial) 5.5-6.5 (Bag)
		Molecular Weight:	290.1g/mol

Section 10 - Stability and Reactivity

Stability: Stable under normal conditions of use.

Incompatibility (Materials to avoid): As a precautionary measure, keep away from strong oxidizers.

Hazardous Decomposition: Not known

Hazardous Polymerization: Will not occur

Conditions to Avoid: Protect from light and temperatures exceeding 86 ºF (30 ºC).

Section 11 - Toxicological Information

Signs & Symptoms of Exposure: Common adverse effects include nausea, vomiting, gastrointestinal irritation, fatigue, decreased red blood cell count (anemia), constipation, fever, shortness of breath (dyspnea) and bone pain.

Acute Toxicity

Component	Type	Route	Species	Dosage
Zoledronic Acid	Minimum Lethal Dose	Intravenous	Mouse	>10 mg/Kg
Zoledronic Acid	Minimum Lethal Dose	Intravenous	Rat	>0.6 mg/Kg

No evidence of carcinogenicity in studies with mice and rats.

Section 12 - Ecological Information

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

Regulatory Organizations:
DOT: Not Regulated
ICAO/IATA: Not Regulated
IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent 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 - *No*
CERCLA - *Not on this list*
SARA 302 - *Not on this list*
SARA 311/312 – *Acute health effects, chronic health effects*
Sara 313 – *Not listed*
OSHA Substance Specific - *No*
RCRA – Not listed

Section 16 - Other Information

As of the date of issuance, 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 MATERIAL 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:
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Glossary: This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
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
NIOSH	National Institute for Occupational Safety and Health
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
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)