Section 1 - Identification

(a) Product Identifier: Zoledronic Acid

(b) NDC: 25021-830-82, 25021-830-87

Common/Trade Name: Reclast®

Chemical Name: (1-Hydroxy-2-imidazol-l-yl-phosphonoethyl) phosphonic acid monohydrate

Chemical Family: Bisphosphonate

(c) Product Use: Treatment of Paget's Disease

Product Type: Regulated Prescription Drug

Container Information: Bag

(d) Distributor: Sagent Pharmaceuticals, 1515 E Woodfield Road Suite 1100, Schaumburg, IL 60173, 847-908-1600

(e) Emergency Telephone: 866-625-1618

Section 2 - Hazards Identification

(a) Classification:

GHS Classification:

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):	**(c) Description of Hazards:**
Signal Word: Symbol	- WARNING 
H361fd	**GHS Hazard Statements:** - Suspected of damaging fertility. Suspected of damaging the unborn child.
P201 P202 P281 P308 + P313 P501	**GHS Precautionary Statements:** - Obtain special instructions before use. - Do not handle until all safety precautions have been read and understood - Use personal protective equipment as required - IF exposed or concerned: Get medical attention/advice - Dispose of contents/container in accordance with local/regional/national/international regulations

(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-Hydroxy-2-imidazol-l-yl-phosphonoethyl) phosphonic acid monohydrate	Zoledronic Acid	0.005% (w/v)	118072-93-8	N/A
(2*R*,3*R*,4*R*,5*R*)-Hexan-1,2,3,4,5,6-hexol	Mannitol	4.95% (w/v)	69-65-8	N/A
Sodium Citrate	Sodium Citrate	pH Adj.	6132-04-3	N/A
Water	Water for Injection	95% (w/v)	7732-18-5	N/A

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.

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 firefighting 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.

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

Single-use only. Discard unused portion.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

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

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

(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.
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
(b)	**Odor**	Not Available

(c)	**Odor Threshold**	Not Available
(d)	**pH**	6.0-7.0
(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)**	Highly 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 normal conditions of use.
(c)	**Possibility of Hazardous Reactions**	Hazardous polymerization will not occur
(d)	**Conditions to Avoid**	Protect from light and temperatures exceeding 86 ºF (30 ºC).
(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 also 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	>10 mg/Kg
Zoledronic Acid	Minimum Lethal Dose	Intravenous	Rat	>0.6 mg/Kg
Mannitol	LD_{50}	Oral	Rat	13500 mg/kg
Mannitol	LD_{50}	Oral	Mouse	22.00 g/kg

(e) Hazardous Chemical Listings

NTP: Not Listed IARC: Not Listed OSHA: Listed NIOSH: Listed
Group 3: Non antineoplastic drugs that primarily have adverse reproductive effects

Section 12 - Ecological Information		
(a)	**Ecotoxicity**	Data is for drug substance and not finished product. *Daphnia Magna* (water flea) Toxicity EC50 after 48 hrs: > 18 mg/L Algae (*selenastrum capricornutum*) Toxicity EbC50 (72 hrs): 5.1 mg/L ErC50 (72 hrs): 15 mg/L NoEC (72 hrs): 2.2 mg/L Bacterial Respiration (Activated Sludge) Inhibition: 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		
(a)	**UN Number**	Not Available
(b)	**UN Proper Shipping Name**	Not Available
(c)	**Transport Hazard Class(es)**	Not Available
(d)	**Packing Group**	Not Available
(e)	**Environmental Hazards**	Not Available
(f)	**Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)**	Not Available
(g)	**Special Precautions**	Not Available

DOT: Not regulated
ICAO/IATA: Not regulated
IMDG: 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 - Listed
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 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:
Sagent Pharmaceuticals
1515 E Woodfield Road Suite 1100, Schaumburg, IL 60173
847-908-1600

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 1980)
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 Association
IMDG	International Maritime Dangerous Goods
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