



MATERIAL SAFETY DATA SHEET

Revision date: 18-Feb-2010

Version: 1.0

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
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1-212-573-2222

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

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+00 44 (0)1304 616161
Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Zoledronic Acid Injection

Trade Name:	Not applicable
Chemical Family:	Bisphosphonate
Intended Use:	Pharmaceutical product

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless solution
Signal Word: DANGER

Statement of Hazard: May damage fertility or the unborn child.

Additional Hazard Information:
Known Clinical Effects:

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

EU Indication of danger: Toxic to reproduction, Category 2

EU Hazard Symbols:



EU Risk Phrases:

R60 - May impair fertility.
R61 - May cause harm to the unborn child.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Zoledronic acid	118072-93-8	Not listed	Repr.Cat.2;R60-61	0.5-1.0
Citric acid	77-92-9	201-069-1	Xi; R36	**

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Mannitol	69-65-8	200-711-8	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	*
Sodium citrate	68-04-2	200-675-3	Not Listed	*

Additional Information: ** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

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

Skin Contact: 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.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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

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

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. Collect spilled material by 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.

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Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for 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.

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. 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 as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Zoledronic acid

Pfizer Occupational Exposure Band (OEB): OEB4 (control exposure to the range of $>1\mu\text{g}/\text{m}^3$ to $<10\mu\text{g}/\text{m}^3$)

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

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

Skin: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solution
Color: Clear, colorless
Molecular Formula: Mixture
Molecular Weight: Mixture

pH: 6.2

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

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10. STABILITY AND REACTIVITY

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

Acute Toxicity: (Species, Route, End Point, Dose)

Mannitol

Rat Oral LD 50 13500 mg/kg
Mouse Oral LD 50 22 g/kg

Zoledronic acid

Mouse Intravenous Minimum Lethal Dose > 10 mg/kg
Rat Intravenous Minimum Lethal Dose > 0.6 mg/kg

Citric acid

Rat Oral LD50 3000 mg/kg

Citric acid

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Zoledronic acid

4 Week(s) Rat Subcutaneous 0.02 mg/kg/day NOAEL Bone
4 Week(s) Dog Intravenous 0.02 mg/kg/day NOAEL Bone

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Zoledronic acid

Reproductive & Fertility Rat Subcutaneous 0.03 mg/kg/day LOAEL Fertility, Fetotoxicity, Maternal toxicity
Embryo / Fetal Development Rat Subcutaneous 0.2 mg/kg/day LOAEL Fetotoxicity
Embryo / Fetal Development Rabbit Subcutaneous 0.01 mg/kg/day LOAEL Maternal Toxicity, Fetal mortality

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Zoledronic acid

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vitro Mammalian Cell Mutagenicity Hamster Negative
In Vivo Micronucleus Rat Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Zoledronic acid

2 Year(s) Mouse Oral 0.1 mg/kg/day LOAEL Benign tumors
2 Year(s) Rat Oral 2 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status:

Not listed as a carcinogen by IARC, NTP or US OSHA.

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12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: 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 wastewater.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic to reproduction, Category 2

EU Risk Phrases:
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

OSHA Label:
DANGER
May damage fertility or the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A



Mannitol

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present

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15. REGULATORY INFORMATION

EU EINECS/ELINCS List 200-711-8

Water for injection

Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List 231-791-2

Citric acid

Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
EU EINECS/ELINCS List 201-069-1

Sodium citrate

Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 5
Schedule 6
EU EINECS/ELINCS List 200-675-3

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R61 - May cause harm to the unborn child.

R60 - May impair fertility.

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet