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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Zoledronic Acid Injection (Hospira, Inc.)

Product Code(s) PZ03169

Synonyms Zoledronic acid concentrate for solution for infusion.

Trade Name: Not applicable Bisphosphonate **Chemical Family:**

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company 275 North Field Drive

Lake Forest, Illinois 60045

1-800-879-3477

Pfizer Ireland Pharmaceuticals

OSG Building

Ringaskiddy, Co. Cork.

Ireland

+353 21 4378701

pfizer-MSDS@pfizer.com E-mail address

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

OSHA Classification

Hazards not otherwise classified (HNOC)

Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

Not applicable

2.2. Label elements

Not classified Signal word

Hazard statements Not classified in accordance with international standards for workplace safety.

2.3. Other hazards

Other hazards An Occupational Exposure Value has been established for one or more of the ingredients Revision date 18-Jun-2025

(see Section 8).

PBT & vPvB The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

This document has been prepared in accordance with standards for workplace safety, which Note:

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

3.1 Substances

Substances Not applicable

3.2 Mixtures

Hazardous

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Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Zoledronic acid (CAS #: 118072-93-8)	<0.1		Not Listed	Repr. 1B (H360FD)	Not classified	No data available	No data available
Citric acid (CAS #: 77-92-9)	**		201-069-1 (607-750-00-3)	Eye Irrit. 2A (H319)SE 3 (H335)	Not classified	No data available	No data available
NonHazardous							
Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available
Sodium citrate (CAS #: 68-04-2)	*	-	200-675-3	Not classified	Not classified	No data available	No data available
Mannitol (CAS #: 69-65-8)	*	-	200-711-8	Not classified	Not classified	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate No information available

Chemical name	Oral LD50 mg/kg	Dermal LD50	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
		mg/kg	hour - dust/mist - mg/L	hour - vapor - mg/L	hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Mannitol	13500	No data available	No data available	No data available	No data available

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Chemical name	Oral LD50 mg/kg	Dermal LD50	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
		mg/kg	hour - dust/mist - mg/L	hour - vapor - mg/L	hour - gas - ppm
69-65-8					
Citric acid 77-92-9	5400	>2000	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

Additional information

* to adjust pH

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret. Non-hazardous ingredients provided for completeness.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation Remove to fresh air. Seek immediate medical attention/advice.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

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.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and

effects

For information on potential signs and symptoms of exposure, See Section 2 - Hazards

Identification and/or Section 11 - Toxicological Information.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

Fine particles (such as dust and mists) may fuel fires/explosions.

chemical

Hazardous combustion products Formation of toxic gases is possible during heating or fire.

Explosion data

Sensitivity to mechanical impact No information available. No information available. Sensitivity to static discharge

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5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see

Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be

taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Prevent further leakage or spillage if safe to do so. **Methods for containment**

Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean Methods for cleaning up

spill area thoroughly.

Clean contaminated objects and areas thoroughly observing environmental regulations. Prevention of secondary hazards

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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.

Handle in accordance with good industrial hygiene and safety practice. General hygiene considerations

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

Refer to available public information for specific member state Occupational Exposure Limits.

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Zoledronic acid

Pfizer OEL TWA-8 Hr: 4 µg/m³

Mannitol Russia

MAC: 10 mg/m³ Citric acid

Czech Republic 4 mg/m³

Germany DFG TWA-MAK: 2 mg/m³; I(2);inhalable fraction

Peak: 4 mg/m³; respirable fraction

Germany TRGS TWA-AGW; 2 mg/m³ (exposure factor 2); inhalable fraction

MAC: 1 mg/m³ Russia

Switzerland TWA-MAK: 2 mg/m3; inhalable dust

STEL-KZGW: 4 mg/m3; inhalable dust

8.2. Exposure controls

Personal protective equipment

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. 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. Refer to applicable national standards and regulations in the

selection and use of personal protective equipment (PPE).

Eye/face protection Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the

standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with

> drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Impervious disposable protective clothing is recommended if skin contact with drug product Skin and body protection

is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is

exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter).

(Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10

or international equivalent.).

Thermal hazards No information available.

Environmental exposure controls No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Solution **Appearance**

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Physical state Liquid

Color Clear, colorless

No information available. Odor **Odor threshold** No information available

Values **Property**

No data available Melting point / freezing point Boiling point or initial boiling point and boiling range No data available

No data available Flammability (solid, gas) Lower and upper explosion limit/flammability limit

Lower explosion limit No data available Upper explosion limit No data available Flash point No data available

Autoignition temperature No data available

Decomposition temperature SADT (°C) No data available

6.2

pН No data available pH (as aqueous solution) Kinematic viscosity No data available Dynamic viscosity No data available Solubility No data available Vapor pressure No data available

Density and/or relative density No data available **Bulk density** No data available **Liquid Density** No data available

No data available Vapor density Particle characteristics

Particle Size No information available **Particle Size Distribution** No information available

9.2. Other information

Molecular formula Mixture Mixture Molecular weight

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stable under normal conditions. Stability

Explosion data

Sensitivity to mechanical impact No information available. Sensitivity to static discharge No information available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

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

10.5. Incompatible materials

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Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Known Clinical Effects: Common adverse effects include nausea, vomiting, gastrointestinal irritation, tiredness,

decreased red blood cell count (anemia), constipation, fever, shortness of breath (dyspnea),

and bone pain.

Acute toxicity
Serious eye damage/eye irritation
Skin corrosion/irritation
Respiratory or skin sensitization
STOT - single exposure
STOT - repeated exposure
Reproductive toxicity
Germ cell mutagenicity
Carcinogenicity

Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met.

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

Zoledronic acid

Aspiration hazard

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

<u>Mannitol</u>

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

Citric acid

Mouse Oral LD50 5400 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50	
Water	> 90 mL/kg (Rat)	-	-	
Mannitol	= 13500 mg/kg (Rat)	-	-	
Citric acid	= 3 g/kg (Rat)	> 2000 mg/kg (Rat)	-	

Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not

achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

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))

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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

Carcinogenicity None of the components of this formulation are listed as a carcinogen by IARC, NTP or

OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Based on available data, the classification criteria are not met. Environmental properties

have not been investigated. Releases to the environment should be avoided.

12.1. Toxicity

12.2. Persistence and degradability

No information available. Persistence and degradability

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment Based on available data, the classification criteria are not met.

Chemical name	PBT and vPvB assessment		
Sodium citrate	Not PBT/vPvB PBT assessment does not apply		

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Not PBT/vPvB Citric acid

12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

No information available. Other adverse effects

PMT or vPvM properties Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

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 wastewater 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.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

UN number: Not applicable UN proper shipping name: Not applicable Transport hazard class(es): Not applicable Packing group: Not applicable Not applicable **Environmental Hazard(s):**

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Zoledronic acid

CERCLA/SARA Section 313 de minimus % Not Listed California Proposition 65 Not Listed Not Listed **EINECS** Standard for Uniform Scheduling of Medicines and Schedule 4

Poisons (SUSMP)

Water

CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed **TSCA** Present

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EINECS 231-791-2 **AICS** Present

Sodium citrate

CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed Present **TSCA EINECS** 200-675-3 **AICS** Present Standard for Uniform Scheduling of Medicines and Schedule 5

Poisons (SUSMP)

Mannitol

CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed Present **TSCA EINECS** 200-711-8 **AICS** Present

Citric acid

CERCLA/SARA Section 313 de minimus % Not Listed Not Listed California Proposition 65 **TSCA** Present 201-069-1 **EINECS AICS** Present

National regulations

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905 Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable **Storage of Hazardous Material** Not applicable WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable Major Accidents Ordinance SR 814.012 Not applicable

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH	Substance subject to authorization per
	Annex XVII	REACH Annex XIV
Citric acid	75	-
77-92-9		

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

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Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)		
Citric acid	Product-type 2: Disinfectants and algaecides not intended		
77-92-9	for direct application to humans or animals Product-type 6:		
	Preservatives for products during storage		

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing Chemicals Inventory

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

TCSI - Taiwan Chemical Substance Inventory

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of any hazard and/or precautionary statements referred to under Sections 2-15

H360FD - May damage fertility. May damage the unborn child

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

Reason for revision Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on

Ingredients. Updated Section 6 - Accidental Release Measures. Updated Section 11 -

Toxicology Information. Updated Section 12 - Ecological Information.

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Prepared By Pfizer Global Environment, Health, and Safety

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