

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

# 73572 - Zoledronic Acid (Hydrate)

Revision Date 24-Apr-2024 Revision Number 2.1

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

1.1. Product identifier

Document Number DX21226

Product Name Zoledronic Acid (Hydrate)

**Synonym** Zoledronate

Pure substance/mixture Substance

Contains (1-Hydroxy-2-imidazol-1-ylethylidene)diphosphonic acid monohydrate

Molecular weight 290.1

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

Recommended Use Laboratory chemicals

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

STEMCELL Technologies SARL

40 Rue des Berges, Miniparc Polytec, Bâtiment Sirocco, 38000 Grenoble, France

+33 (0) 4 76 04 75 30

STEMCELL Technologies Germany GmbH

Stolberger Str. 200, 50933, Köln, Germany

+33 (0) 4 76 04 75 30

STEMCELL Technologies UK Ltd.

Building 7100, Cambridge Research Park, Beach Drive, Waterbeach, Cambridge, UK, CB25 9TL

+33 (0) 4 76 04 75 30

For further information, please contact

1.4. Emergency telephone number

Emergency Telephone No information available

Emergency Telephone - §45 - (EC)1272/2008

Europe 112

# Section 2: HAZARDS IDENTIFICATION

#### 2.1. Classification of the substance or mixture



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision Date 24-Apr-2024 Revision Number 2.1

# 73572 - Zoledronic Acid (Hydrate)

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Regulation (EC) No 1272/2008

Skin corrosion/irritation	Category 2 - (H315)
Serious eye damage/eye irritation	Category 2 - (H319)
Specific target organ toxicity (single exposure)	Category 3 - (H335)

# 2.2. Label elements

Contains (1-Hydroxy-2-imidazol-1-ylethylidene)diphosphonic acid monohydrate



Signal word Warning

#### **Hazard statements**

#### **Hazard statements**

H315 - Causes skin irritation

H319 - Causes serious eye irritation

H335 - May cause respiratory irritation

### 2.3. Other hazards

No information available

# **Section 3: COMPOSITION/INFORMATION ON INGREDIENTS**

### 3.1 Synonym

Chemical name	EC No.	CAS No.	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
(1-Hydroxy-2-imidazol-1-ylethylidene) diphosphonic acid monohydrate	-	165800-06-6	100	Skin Irritation – Skin Irrit. 2 (H315) Eye Irritation – Eye Irrit. 2a (H319) Specific Target Organ Toxicity – Single Exposure – STOT SE 3 (H335)	No data available

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



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

73572 - Zoledronic Acid (Hydrate)

Revision Date 24-Apr-2024 Revision Number 2.1

### Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

**General advice** Show this safety data sheet to the doctor in attendance.

Inhalation Remove to fresh air. IF exposed or concerned: Get medical advice/attention. Get medical

attention immediately if symptoms occur.

**Eye contact** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep

eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists. Do not rub affected area.

**Skin contact** Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical

attention if irritation develops and persists.

**Ingestion** Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water.

Never give anything by mouth to an unconscious person. Call a physician.

**Self-protection of the first aider** Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

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

**Symptoms** Burning sensation.

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

# Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

surrounding environment.

**Unsuitable Extinguishing Media** No information available.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

No information available.

5.3. Advice for firefighters

Special protective equipment for

fire-fighters

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

gear. Use personal protection equipment.



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

73572 - Zoledronic Acid (Hydrate)

Revision Date 24-Apr-2024 Revision Number 2.1

# **Section 6: ACCIDENTAL RELEASE MEASURES**

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation. Use personal protective equipment as required. Evacuate

personnel to safe areas. Avoid contact with skin, eyes or clothing.

**Other Information** Refer to protective measures listed in Sections 7 and 8.

For emergency responders

Use personal protection recommended in Section 8.

6.2. Environmental precautions

**Environmental precautions** Prevent further leakage or spillage if safe to do so.

6.3. Methods and material for containment and cleaning up

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

**Methods for cleaning up**Take up mechanically, placing in appropriate containers for disposal.

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

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 Handle in accordance with good industrial hygiene and safety practice. Avoid contact with

skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse. Ensure adequate ventilation. Avoid breathing vapors or mists. In case of insufficient ventilation, wear suitable respiratory equipment.

General hygiene considerations Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this

product. Avoid contact with skin, eyes or clothing.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store in accordance with information listed on the Product Information Sheet (PIS).

7.3. Specific end use(s)



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

# 73572 - Zoledronic Acid (Hydrate)

Revision Date 24-Apr-2024 Revision Number 2.1

**Identified Uses** 

Risk Management Methods (RMM) The information required is contained in this Material Safety Data Sheet.

# Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.

**Derived No Effect Level (DNEL)**No information available.

**Predicted No Effect Concentration** 

(PNEC)

No information available.

8.2. Exposure controls

Personal protective equipment

**Eye/face protection** If splashes are likely to occur, wear safety glasses with side-shields.

**Hand protection** Wear suitable gloves. Impervious gloves.

**Skin and body protection** Wear suitable protective clothing. Long sleeved clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this

product. Avoid contact with skin, eyes or clothing.

**Environmental exposure controls** No information available.

# **Section 9: PHYSICAL AND CHEMICAL PROPERTIES**

9.1. Information on basic physical and chemical properties

Physical state Solid Appearance Crystalline

Page 5/12



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

None known

# 73572 - Zoledronic Acid (Hydrate)

Revision Date 24-Apr-2024 Revision Number 2.1

ColorNo information availableOdorNo data available.Odor thresholdNo data available

**Property** Values Remarks • Method рΗ No data available None known Melting point / freezing point No data available None known Boiling point / boiling range No data available None known Flash point No data available None known **Evaporation rate** No data available None known Flammability (solid, gas) Product is not flammable. None known

Flammability Limit in Air
Upper flammability limit:
No data available

Upper flammability limit: No data available Lower flammability limit: No data available Vapor pressure No data available

None known None known Vapor density No data available Relative density No data available None known Water solubility No data available None known Solubility(ies) PBS (pH 7.2): 1.6 mg/mL None known No data available Partition coefficient None known **Autoignition temperature** No data available None known **Decomposition temperature** No data available None known Kinematic viscosity No data available None known Dynamic viscosity No data available None known

**Explosive properties**No information available

Oxidizing properties No information available

9.2. Other information

**Softening point** No information available

Molecular weight 290.1

Molecular formulaC5H10N2O7P2 • H2OVOC Content (%)No information availableLiquid DensityNo information availableBulk densityNo information available

# **Section 10: STABILITY AND REACTIVITY**

10.1. Reactivity

**Reactivity** No information available.

10.2. Chemical stability

Stability Stable under recommended transport or storage conditions.

Page 6/12



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

# 73572 - Zoledronic Acid (Hydrate)

Revision Date 24-Apr-2024 Revision Number 2.1

**Explosion data** 

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None. 10.3. Possibility of hazardous reactions

**Possibility of hazardous reactions** None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials Strong oxidizing agents.

10.6. Hazardous decomposition products

Hazardous decomposition products Carbon monoxide. Carbon dioxide (CO2). Nitrogen oxides (NOx). Phosphorus oxides.

### Section 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on toxicological effects

#### Information on likely routes of exposure

#### **Product Information**

**Inhalation** Specific test data for the substance or mixture is not available. May cause irritation of

respiratory tract.

**Eye contact** Specific test data for the substance or mixture is not available. Irritating to eyes. (based on

components). Causes serious eye irritation.

**Skin contact** Specific test data for the substance or mixture is not available. Causes skin irritation. (based

on components).

**Ingestion** Specific test data for the substance or mixture is not available. Ingestion may cause

gastrointestinal irritation, nausea, vomiting and diarrhea.

Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** Redness. May cause redness and tearing of the eyes.

Numerical measures of toxicity



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision Date 24-Apr-2024 Revision Number 2.1

# 73572 - Zoledronic Acid (Hydrate)

#### **Acute toxicity**

**Unknown acute toxicity** 100 % of the mixture consists of ingredient(s) of unknown toxicity.

100 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.

100 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor).

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

#### Product Information

### Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	Classification based on data available for ingredients. Irritating to skin.		
Product Information			
Serious eye damage/eye irritation	Classification based on data available for ingredients. Irritating to eyes.		
Product Information			
Respiratory or skin sensitization	No information available.		
Product Information			
Germ cell mutagenicity	No information available.		
Product Information			
Carcinogenicity	No information available.		
Product Information			
Reproductive toxicity	No information available.		
	Product Information		
STOT - single exposure	May cause respiratory irritation.		
Product Information			
STOT - repeated exposure	No information available.		
Product Information			
Aspiration hazard	No information available.		

# **Section 12: ECOLOGICAL INFORMATION**

12.1. Toxicity

**Ecotoxicity** The environmental impact of this product has not been fully investigated.

Page 8/12



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

# 73572 - Zoledronic Acid (Hydrate)

Revision Date 24-Apr-2024 Revision Number 2.1

**Unknown aquatic toxicity**Contains 100 % of components with unknown hazards to the aquatic environment.

**Product Information** 

12.2. Persistence and degradability

Persistence and degradability No information available.

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**No information available.

12.6. Other adverse effects

Other adverse effects No information available.

# **Section 13: DISPOSAL CONSIDERATIONS**

13.1. Waste treatment methods

Waste from residues/unused products

Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging

Do not reuse empty containers.

# **Section 14: TRANSPORT INFORMATION**

**IMDG** 

14.1 UN NumberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing GroupNot regulated14.5 Marine pollutantNot applicable

Page 9/12



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision Date 24-Apr-2024
Revision Number 2.1

# 73572 - Zoledronic Acid (Hydrate)

14.6 Special Provisions None

14.7. Transport in bulk according to No information available

Annex II of MARPOL and the IBC

Code

RID

14.1 UN NumberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing GroupNot regulated14.5 Environmental hazardNot applicable

14.6 Special Provisions None

ADR

14.1 UN NumberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing GroupNot regulated14.5 Environmental hazardNot applicable

14.6 Special Provisions None

IATA Not regulated

14.1 UN NumberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing GroupNot regulated14.5 Environmental hazardNot applicable

14.6 Special Provisions None

# **Section 15: REGULATORY INFORMATION**

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

### **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)

#### **Persistent Organic Pollutants**

Not applicable



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

73572 - Zoledronic Acid (Hydrate)

Revision Date 24-Apr-2024 Revision Number 2.1

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

#### **International Inventories**

**TSCA** Does not comply **DSL/NDSL** Does not comply **EINECS/ELINCS** Does not comply **ENCS** Does not comply **IECSC** Does not comply **KECL** Does not comply **PICCS** Does not comply **AICS** Does not comply

#### 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 and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

### 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 H-Statements referred to under section 3

H315 - Causes skin irritation

H319 - Causes serious eye irritation

H335 - May cause respiratory irritation

#### Leaend

SVHC: Substances of Very High Concern for Authorization:

### Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value \* Skin designation

Revision Date 24-Apr-2024

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73572 - Zoledronic Acid (Hydrate)

Revision Date 24-Apr-2024 Revision Number 2.1

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

#### **Disclaimer**

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