

PRODUCT AND COMPANY IDENTIFICATION

GHS Product Name: Zoledronic acid hydrate
Product code: h-313
Company: PharmSintez.Lab
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1.1 Product identifiers

Product name:	Zoledronic acid hydrate
Product Catalogue Number:	h-313
Band:	PharmSintez.Lab
CAS-No:	165800-06-6

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

Identified uses:	Laboratory chemicals, Synthesis of substances.
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1. HAZARDS IDENTIFICATION

1.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Skin irritation (Category 2), H315
 Serious eye damage (Category 1), H318
 Respiratory sensitisation (Category 1), H334
 Skin sensitisation (Category 1), H317
 Germ cell mutagenicity (Category 2), H341
 Reproductive toxicity (Category 2), H361
 Specific target organ toxicity - single exposure (Category 1), H370
 Specific target organ toxicity - single exposure (Category 3), Respiratory system, H335
 Chronic aquatic toxicity (Category 4), H413
 For the full text of the H-Statements mentioned in this Section, see Section 16.

1.2 GHS Label elements, including precautionary statements

Pictogram:



Signal word:

Danger

Hazard statement(s)

H315: Causes skin irritation.
 H317: May cause an allergic skin reaction
 H318: Causes serious eye damage.
 H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 H335: May cause respiratory irritation.
 H341: Suspected of causing genetic defects.
 H361: Suspected of damaging fertility or the unborn child.
 H370: Causes damage to organs.
 H413: May cause long lasting harmful effects to aquatic life.

Precautionary statement(s)

P201:	Obtain special instructions before use.
P202:	Do not handle until all safety precautions have been read and understood.
P260:	Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.
P264:	Wash skin thoroughly after handling.
P270:	Do not eat, drink or smoke when using this product.
P271:	Use only outdoors or in a well-ventilated area.
P272:	Contaminated work clothing should not be allowed out of the workplace.
P273:	Avoid release to the environment.
P280:	Wear protective gloves/ eye protection/ face protection.
P302 + P352:	IF ON SKIN: Wash with plenty of soap and water.
P304 + P340:	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305 + P351 + P338:	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310:	Immediately call a POISON CENTER/doctor.
P321:	Specific treatment (see supplemental first aid instructions on this label).
P333 + P313:	If skin irritation or rash occurs: Get medical advice/ attention.
P362:	Take off contaminated clothing and wash before reuse.
P403 + P233:	Store in a well-ventilated place. Keep container tightly closed.
P405:	Store locked up.
P501:	Dispose of contents/ container to an approved waste disposal plant.

1.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none**2. COMPOSITION/INFORMATION ON INGREDIENTS****2.1 Substances**

Synonyms:	CGP 42446; CGP42446A; ZOL 446; zoledronate; zoledronate. brand name: Zometa; Reclast
Formula:	C ₅ H ₁₂ N ₂ O ₈ P ₂
Molecular weight:	290.1
CAS-No:	165800-06-6

Hazardous components

Component	Classification	Concentration
Zoledronic acid hydrate	Skin Irrit. 2; Eye Dam. 1; Resp. Sens. 1; Skin Sens. 1; Muta. 2; Repr. 2; STOT SE 3; Aquatic Chronic 4; H315, H317, H318, H334, H335, H341, H361, H413	<= 100 %

For the full text of the H-Statements mentioned in this Section, see Section 16.

3. FIRST AID MEASURES**3.1 Description of first aid measures****General advice**

Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

3.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

3.3 Indication of any immediate medical attention and special treatment needed

No data available

4. FIREFIGHTING MEASURES

4.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

4.2 Special hazards arising from the substance or mixture

No data available

4.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

4.4 Further information

No data available

5. ACCIDENTAL RELEASE MEASURES

5.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

For personal protection see section 8.

5.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

5.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

5.4 Reference to other sections

For disposal see section 13.

6. HANDLING AND STORAGE

6.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.2.

6.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place.

Recommended storage temperature: 2 - 8 °C for short term (weeks to 3 months) or -20°C for long term (3 months to years).

Keep in a dry place.

6.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

7. EXPOSURE CONTROLS/PERSONAL PROTECTION

7.1 Control parameters

Components with workplace control parameters

Compone	CAS-No.	Value	Control parameters	Basis
Zoledroni c acid	165800-06-6	N/A	N/A	N/A

7.2 Exposure controls**Appropriate engineering controls**

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment**Eye/face protection**

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Body Protection

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

8. PHYSICAL AND CHEMICAL PROPERTIES**8.1 Information on basic physical and chemical properties**

a) Appearance Form:	Color: White Form: Solid powder
b) Odour	No data available
c) Odour Threshold	No data available
d) pH	No data available
e) Melting point/freezing point	No data available
f) Initial boiling point and boiling range	No data available
g) Flash point	No data available
h) Evaporation rate	No data available
i) Flammability (solid, gas)	No data available
j) Upper/lower flammability or explosive limits	No data available
k) Vapour pressure	No data available
l) Vapour density	No data available
m) Relative density	No data available
n) Water solubility	Insoluble

o) Partition coefficient: noctanol/ water	log Pow: > 99
p) Auto-ignition	No data available
q) Decomposition	No data available
r) Viscosity	No data available
s) Explosive properties	No data available
t) Oxidizing properties	No data available

8.2 Other safety information

No data available

9. STABILITY AND REACTIVITY

9.1 Reactivity : No data available

9.2 Chemical stability: Stable under recommended storage conditions.

9.3 Possibility of hazardous reactions: No data available

9.4 Conditions to avoid: No data available

9.5 Incompatible materials: No data available

9.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides (NOx)

Other decomposition products - No data available

In the event of fire: see section 5

10. TOXICOLOGICAL INFORMATION

10.1 Information on toxicological effects

Acute toxicity	No data available
Inhalation:	No data available
Inhalation:	Irritating to respiratory
Dermal	No data available

Skin corrosion/irritation: No data available

Serious eye damage/eye irritation: No data available

Respiratory or skin sensitisation

Germ cell mutagenicity: No data available

Hamster: No data available

Lungs: No data available

Cytogenetic analysis: No data available

Mouse: No data available

Micronucleus test: No data available

Carcinogenicity

IARC:	No component of this product present at levels greater than or equal to 0.1% is identified as probable,
NTP:	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
OSH A:	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

Reproductive toxicity - Rat - No data available

Maternal Effects: No data available

Reproductive toxicity - Rat - No data available
Effects on Newborn: No data available
Developmental Toxicity - Rat - No data available
Specific Developmental Abnormalities: No data available

Specific target organ toxicity - single exposure Inhalation - May cause respiratory irritation.

Specific target organ toxicity - repeated exposure: No data available

Aspiration hazard: No data available

Additional Information

RTECS: DA8340700

Alopecia., Liver injury may occur., Kidney injury may occur., Nausea, Headache, Vomiting, bone marrow depression

Stomach - Irregularities - No data available

Central nervous system - No data available

Kidney - Irregularities - No data available

Heart - Irregularities - No data available

Stomach - Irregularities - No data available

Stomach - Irregularities - No data available

Kidney - Irregularities - No data available

Stomach - Irregularities - No data available

11. ECOLOGICAL INFORMATION

11.1 Toxicity: No data available

11.2 Persistence and degradability: No data available

11.3 Bioaccumulative potential: No data available

11.4 Mobility in soil: No data available

11.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

11.6 Other adverse effects: No data available

12. DISPOSAL CONSIDERATIONS

12.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging

Dispose of as unused product.

13. TRANSPORT INFORMATION

DOT (US): Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

14. OTHER INFORMATION**Full text of H-Statements referred to under sections 2 and 3.**

Acute Tox.	Acute toxicity
Aquatic Chronic	Chronic aquatic toxicity
Eye Dam.	Serious eye damage
Eye Irrit.	Eye irritation
Flam. Liq.	Flammable liquids
H225	Highly flammable liquid and vapour.
H301 + H311 +	Toxic if swallowed, in contact with skin or if inhaled
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H341	Suspected of causing genetic defects.
H361	Suspected of damaging fertility or the unborn child.
H370	Causes damage to organs.
H413	May cause long lasting harmful effects to aquatic
Muta.	Germ cell mutagenicity
Repr.	Reproductive toxicity
Resp. Sens.	Respiratory sensitisation
Skin Irrit.	Skin irritation
Skin Sens.	Skin sensitisation
STOT SE	Specific target organ toxicity - single exposure

HMIS Rating

Health hazard: 2
 Chronic Health Hazard: *
 Flammability: 0
 Physical Hazard 0

NFPA Rating

Health hazard: 2
 Fire Hazard: 0
 Reactivity Hazard: 0

Further information

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Preparation Information

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