

Safety Data Sheet Calcifediol Monohydrate

SECTION 1: Product and Company Identification

1) Product identification

Product Name: Calcifediol Monohydrate

Standard: USP40

CAS Number: 63283-36-3

2) Recommended use of the chemical and restrictions on use

Identified uses: Laboratory chemicals, Manufacture of substances

3) Details of the supplier of the safety data sheet

Company: Heron (Shanghai) Pharmaceutical Science and Technology Co., LTD.

Room 413 Wolicity Building B, No. 2419 Hunan Road, Pudong New Area District, Shanghai 201204, China

Tel: +86-21-5847-9828

4) Emergency telephone number

Emergency Phone: +86-150-2187-4276

SECTION 2: Hazard Identification

2.1 Classification of the substance or mixture

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

Acute toxicity, Oral (Category 2), H300

Acute toxicity, Inhalation (Category 1), H330

Acute toxicity, Dermal (Category 2), H310

Specific target organ toxicity - repeated exposure, Oral (Category 1), H372

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

2.2 GHS Label elements, including precautionary statements



1) GHS pictogram

2) GHS signal word: Danger

Hazard statement(s)

H300 + H310 + H330 Fatal if swallowed, in contact with skin or if inhaled.

H372 Causes damage to organs through prolonged or repeated exposure if swallowed.

H413 May cause long lasting harmful effects to aquatic life.

Precautionary statement(s)

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P262 Do not get in eyes, on skin, or on clothing.

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.

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing.

P284 Wear respiratory protection.

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P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER/doctor. Rinse mouth.

P302 + P350 + P310 IF ON SKIN: Wash with plenty of water. Call a POISON CENTER/doctor if you feel unwell.

P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/doctor.

P314 Get medical advice/attention if you feel unwell.

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.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

SECTION 3: Composition/Information on Ingredients Substances

Component: Calcifediol Monohydrate

CAS Number: 63283-36-3

Formula: $C_{27}H_{46}O_3$

Molecular Weight: 418.66

SECTION 4: First-Aid Measures

4.1 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

Flush eyes with water as a precaution.

If swallowed

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

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Fire-fighting Measures

5.1 Extinguishing media

Suitable extinguishing media.

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

5.2 Special hazards arising from the substance or mixture

No data available

5.3 Advice for firefighters

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Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

SECTION 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. For personal protection see section 8.

6.2 Environmental precautions

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

6.3 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.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and Storage

7.1 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. Normal measures for preventive fire protection. For precautions see section 2.

7.2 Conditions for safe storage, including any incompatibilities

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

Store temperature: In an airtight container, under an inert gas, protected from light. Avoid contact with water and humidity.

7.3 Specific end use(s)

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

SECTION 8: Exposure Controls/Personal Protection

8.1 Control parameters

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Hazardous components without workplace control parameters.

8.2 Exposure controls

Appropriate engineering controls

Good general ventilation should be sufficient to control airborne levels. Ventilation is normally required when handling or using this product. Eyewash fountains should be provided in areas where there is any possibility that workers could be exposed to the substance. Follow safe industrial engineering/laboratory practices when handling any chemical.

Personal protective equipment

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

Respiratory protection: Dust respirator. Be sure to use a MSHA/NIOSH approved respirator or equivalent.

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Hand protection: Nitrile gloves.

Eye protection: Safety glasses.

Skin and body protection: Lab coat.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face supplied air respirator.

Control of environmental exposure

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

SECTION 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Product Name: Calcifediol Monohydrate

Appearance: White crystalline powder

Odor: No data available

Odor threshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: No data available

Evaporation rate: No data available

Flammability: No data available

Upper/lower flammability or explosive limits: No data available

Vapor pressure: No data available

Vapor density: No data available

Relative density: No data available

Solubility(ies): Soluble in anhydrous ethanol and in ethyl acetate, practically insoluble in water.

Partition coefficient: n-octanol/water: log pow: 9.4

Auto-ignition temperature: No data available

Decomposition temperature: No data available

Viscosity: No data available

SECTION 10: Stability and Reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

Strong acids and oxidizing agents

10.6 Hazardous decomposition products

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Hazardous decomposition products formed under fire conditions: Carbon oxides.

In the event of fire: see section 5

SECTION 11: Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

No data available

Inhalation: No data available

Dermal: No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitisation

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

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.

OSHA: 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

No data available

Routes of Exposure: Inhalation, Eye contact, Ingestion, Skin contact

Specific target organ toxicity: No data available

Aspiration hazard: No data available

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12: Ecological Information

12.1 Toxicity

No data available.

12.2 Persistence and degradability

No data available.

12.3 Bio-accumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment unavailable as chemical safety assessment not required or not conducted.

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12.6 Other adverse effects

No data available.

SECTION 13: Disposal Information**1) Disposal of product**

It is the generator's responsibility to comply with Local rules and regulations. The product should not be allowed to enter the environment, drains, water ways, or the soil. 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. Offer surplus and non-recyclable solutions to a licensed disposal company.

2) Disposal of container

Dispose of as unused product. Do not re-use empty containers.

3) Other considerations

Observe all federal, state and local regulations when disposing of the substance.

SECTION 14: Transport Information

UN Number: 2811

Class: 6.1

Packing Group: II

Proper shipping name: Calcifediol Monohydrate (25-Hydroxyvitamin D3 monohydrate)

Poison Inhalation Hazard: No

SECTION 15: Regulatory Information**SARA 302 Components**

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components

This material does not contain any chemical components with known CAS numbers that exceed the threshold (DeMinimis) reporting levels established by SARA Title III, Section 313.

This product does not contain any chemicals known to cause cancer, birth defects, or any other reproductive harm.

SECTION 16: Other Information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of calcifediol. Heron Pharma Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. Final determination of suitability of any material is the sole responsibility of the user. All chemical reagents must be handled with the recognition that their chemical, physiological, toxicological, and hazardous properties have not been fully investigated or determined. All chemical reagents should be handled only by individuals who are familiar with their potential hazards and who have been fully trained in proper safety, laboratory, and chemical handling procedures. Avoid long storage periods since calcifediol is subject to degradation with age and may become more dangerous or hazardous. Disposal of unused product must be under taken by qualified personnel who are

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knowledgeable in all applicable regulations and follow all pertinent safety precautions including the use of appropriate protective equipment (e.g. protective goggles, protective clothing, breathing equipment, face mask, fume hood). For proper handling and disposal, always comply with federal, state and local regulations.