

**Safety Data Sheet**  
**Alfacalcidol Soft Gelatin Capsules**

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that is accurate. However, this safety data sheet does not constitute a warranty of any kind, express or implied. In the event of an adverse incident associated with this material, this safety data sheet is not, and is not intended to be substitute for consultation with appropriately trained personnel. This is safety data sheet intended to be a substitute for product literature, which may accompany the finished product.

**Section 1 – Chemical Product & Company Identification**

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Product Name: Alfacalcidol Soft Gelatin Capsules

**Section 2 – Composition/Information of Ingredients**

Mixture Ingredients Listed Below:

Common or Chemical Name	CAS Number	Percent in Mixture (%)
Alfacalcidol	41294-56-8	4 ppm
Ethyl Alcohol Absolute, Pharmaceutical Grade	64-17-5	0.64
Alpha-Tocopherol, Pharma Grade	10191-41-0	0.03
Soybean Oil, Pharma Grade	8001-22-7	63.01
Gelatin, Pharma Grade	9000-70-8	29.85
Glycerin, Pharma Grade	56-81-5	5.97
Potassium Sorbate, Pharma Grade	24634-61-5	0.03
Titanium Dioxide, Pharma Grade	NA	0.08
Ferric Oxide Red, Pharma Grade	1332-37-2	0.40
Total		100.00

**Section 3 – Hazards Identification**

**Classification of the mixture**

**Classification according to Regulation (EC) No 1272/2008 [GHS/GLP]**

Acute Toxicity, oral – Category 1

Pictogram:



Signal Word:	Danger
Statements of Hazard:	Fatal if swallowed too much
Additional Data:	For a more detailed discussion of potential health hazards and toxicity see Section 11.
Note:	This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regard less 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 4 – First-Aid Measures**

**Heron(Shanghai) Pharmaceutical Science & Technology Co., Ltd.**

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**General Advice:** Consult a doctor and show this safety data sheet

**Eyes:** No first aid is normally required.

**Skin:** No first aid is normally required.

**Inhalation:** No first aid is normally required.

**Ingestion:** Rinse mouth with water. Do not induce vomiting unless directed to do so by medical person. Never give anything by mouth to an unconscious person. Consult a doctor.

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#### Section 5 – Fire Fighting Measures

**General Hazard:** This material is not a fire hazard under normal conditions.

**Fire Fighting Instructions:** Wear approved positive pressure, self-contained breathing apparatus and full protective turn our gear.

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

**Flash Point:** Not applicable.

**Hazardous Combustion Products:** No data available.

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#### Section 6 – Accidental Release Measures

**Small Spills:** Vacuum sweep material into appropriate recovery container. Clean spill area thoroughly.

**Large Spills:** Contain the source of the spill or leak if it is safe to do so. Vacuum or sweep material into appropriate recovery container. Clean spill area thoroughly.

**General:** Review section 3, 8 and 12 before proceeding with clean up.

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#### Section 7 – Handling and Storage

**General handling:** No special handling requirements for normal use of this material.

**Storage conditions:** Store at 35-65% relative humidity.

**Temperature range for storage:** 15-30°C.

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#### Section 8 – Exposure Controls/Personal Protection

**Ventilation:** Good room ventilation should be sufficient to control airborne levels.

**Eye Protection:** Goggles

**Skin Protection:** Not required under normal and foreseeable conditions of use.

**Hand Protection:** Latex/Nitrile gloves.

**Respiratory Protection:** Not required under normal and foreseeable conditions of use.

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#### Section 9 – Physical and Chemical Properties

**Physical Form:** Soft Gelatin Capsule.

**Color:** According to the product specification.

**Odor:** None.

**Molecular Weight:** Mixture.

**Molecular Formula:** Not applicable.

**pH value:** No data available.

**Boiling Point:** No data available.

**Melting Point:** No data available.

**Density:** Variable.

**Vapor Pressure:** No data available.

**Water Solubility:** Not soluble in water.

**Flammability:** No data available

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#### Section 10 – Stability and Reactivity

**Reactivity:** Stable under normal conditions of use.

**Conditions to avoid:** None known

**Incompatibility:** None known.

**Hazardous Decomposition:** None known.

**Hazardous Polymerization:** No data available.

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#### Section 11 – Toxicology Information

**Toxicology summary:** When used and handled according to specification, the product does not have any harmful effects according to our experience and the information provided to us.

**Acute toxicity:**

**Eye:** No data available.

**Skin:** No data available.

**Inhalation:** No data available.

**Ingestion:** Alfacalcidol, Oral Rat LD50, 0.34 mg/kg

**Mutagenicity:** No data available.

**Subchronic Effects:** No data available.

**Chronic effects/carcinogenicity:** No data available.

**Carcinogen status:** No data available.

**Reproductive Effects:** No data available.

**Teratogenicity:** No data available.

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#### Section 12 – Ecological Information

**Environmental overview:** Not known to be hazardous to water.

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#### Section 13 – Disposal Information

**Disposal procedure:** Observe all federal, state and local regulations when disposing of this material.

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#### Section 14 – Transportation Information

**General Shipping Instructions:** Not regulated for transport under USDOT, EUADR, IATA, or IMDG.

**Hazard Class:** Not applicable.

**Packaging Group:** Not applicable.

**Subsidiary Hazard:** Not applicable.

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#### Section 15 – Regulatory Information

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

No data available

**Chemical safety assessment**

For this product a chemical safety assessment was not carried out

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**Section 16 – Other**

**Disclaimer:** Heron Pharma believes that the information contained in this Material Safety Data Sheet is accurate. While Heron Pharma provides this information in good faith, it does not expressly or impliedly warrant its accuracy.