

# SAFETY DATA SHEET

## Calcitriol capsules 0.25/0.5 MCG

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING.

<b>Product Name:</b>	Calcitriol capsules
<b>Chemical Name:</b>	9,10-seco(5Z,7E)-5,7,10(19) cholestatriene-1 $\alpha$ , 3 $\beta$ , 25-triol
<b>Chemical formula:</b>	C <sub>27</sub> H <sub>44</sub> O <sub>3</sub>
<b>Molecular weight:</b>	416.65
<b>Company Name:</b>	Strides Arcolab Ltd, Opp to IIM, Bilekahalli, Arekare main Road, Bangalore-560076
<b>How supplied:</b>	0.25 & 0.5 mcg
<b>Use:</b>	Pharmaceutical active substance for the treatment of hypocalcemia, management of hypoparathyroidism and metabolic bone disease.

### 2. COMPOSITION / INFORMATION ON INGREDIENTS

<b>Characterization:</b>	Calcitriol and other inactive ingredients	
<b>Ingredients</b>	<b>CAS</b>	<b>Concentration</b>
Calcitriol	32222-06-3	0.0000961 % (0.25 mcg) & 0.000192 % (0.50 mcg)
Medium-chain triglycerides	85409-09-2	61.5 %
Gelatin	9000-70-8	27.3 %
Glycerol	56-81-5	

### 3. HAZARDS IDENTIFICATION

<b>Emergency overview:</b>	Physical State: Calcitriol capsules 0.25 mcg are soft gelatin, orange, oval capsules, imprinted with 673 and Calcitriol capsules 0.5 mcg are soft gelatin, orange, oblong capsules, imprinted with 674. Odor: None WARNING! May be harmful if swallowed. Accidental ingestion of large amounts may be harmful.
<b>Primary Route(s) of Entry:</b>	Ingestion
<b>Potential Health Effects:</b>	<b>Inhalation:</b> Not expected to be an inhalation hazard in final pharmaceutical form. <b>Eye Contact:</b> Not expected to be a hazard to the eye in final pharmaceutical form. <b>Skin Contact:</b> Not expected to be a hazard to the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation. <b>Ingestion:</b> May be harmful if ingested. Ingestion may cause weakness, nausea, vomiting, constipation and anorexia.

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<b>Effects of Overexposure:</b>	The potential for exposure is reduced in finished pharmaceutical form. Overexposure by ingestion may cause weakness, increased thirst, painful urination, chills, irregular heartbeat and hallucinations.
<b>Target Organs:</b>	Gastrointestinal tract

### 4. FIRST-AID MEASURES

<b>Ingestion:</b>	If accidentally ingested contact a physician or a Poisons Information centre.
<b>Skin Contact:</b>	Remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents
<b>Eye Contact:</b>	Rinse immediately with tap water for 10 minutes - open eyelids forcibly.
<b>Indication of any immediate medical attention and special treatment needed</b>	
<b>Note to physician:</b>	Treat symptomatically

### 5. FIRE-FIGHTING MEASURES

<b>Extinguishing Media:</b>	Suitable extinguishing media - adapt extinguishing media to surrounding fire conditions
<b>Specific hazards:</b>	No particular hazards known
<b>Protection of fire-fighters:</b>	Precipitate gases/vapours/mists with water spray

### 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions :</b>	No special precautions required
<b>Environmental Precautions :</b>	Do not allow to enter drains or waterways
<b>Clean-up Methods :</b>	Take up mechanically and dispose of.
<b>Decontamination Procedures:</b>	No specific decontamination or detoxification procedures have been identified for this product.

### 7. HANDLING AND STORAGE

<b>General Requirements :</b>	Avoid breaking or crushing capsules.
<b>Storage :</b>	Store at 20° to 25°C (68° to 77°F) [See USP controlled Room Temperatures] and protected from light.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<b>Threshold value air:</b>	IOEL (Internal Occupational Exposure Limit): 0.01 µg/m <sup>3</sup> (Internal Occupational Exposure Limit, defined as 8-hour time-weighted average)
<b>Respiratory protection:</b>	Respiratory protection not necessary during normal operations
<b>Hand protection:</b>	Protective gloves (eg made of neoprene, nitrile or butyl rubber)
<b>Eye protection:</b>	Safety glasses

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Colour:</b>	Country-specific
<b>Physical Form:</b>	Gelatin capsule soft
<b>Other information:</b>	No information available

### 11. TOXICOLOGICAL INFORMATION

<b>Acute toxicity:</b>	LD <sub>50</sub> < 5 mg/kg (oral, rat) LD <sub>50</sub> 1.3 mg/kg (oral, mouse)
<b>Local effects:</b>	Skin: non-irritant (rabbit) Skin: non-irritant (guinea pig) Eye: non-irritant (rabbit)
<b>Sensitization:</b>	Non-sensitizing (guinea pig)
<b>Chronic toxicity:</b>	Chronic overdoses cause loss of body weight, growth inhibition, weakness, sensoric disorders, excessive urination, loss of water, fever with thirst, infections of urinary passages and apathy. They cause, circumstances permitting, formation of renal calculus, demineralization of the bones and formation of focusses of calcification in lung and kidneys up to renal insufficiency.
<b>Mutagenicity:</b>	Not mutagenic (Ames test)
<b>Reproductive toxicity:</b>	Based on secondary effects (hypercalcemia), the substance may eventually lead to teratogenicity when overdosed

### 12. ECOLOGICAL INFORMATION

<b>ECOTOXICITY:</b>	Barely toxic for algae (nominal concentration = 100 mg/l), test performed with water accommodated fractions (Scenedesmus (=Desmodesmus) subspicatus) EC <sub>50</sub> (72 h) > 100 mg/l (nominal concentration) NOEC (72 h) 0.47 mg/l (average measured concentration) (OECD No. 201) barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l), test performed with water accommodated fractions (Daphnia magna) EC <sub>50</sub> (48 h) > 100 mg/l (nominal concentration) NOEC (48 h) 0.69 mg/l (average measured concentration) (OECD No. 202) barely toxic for fish (nominal concentration = 100 mg/l) (zebrafish) LC <sub>50</sub> (96 h) > 100 mg/l (nominal concentration) NOEC (96 h) 100 mg/l (nominal concentration) (OECD No. 203, semi-static) no adverse influence on substrate biodegradation
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(activated sludge)concentration (28 d) 100 mg/l (nominal concentration)  
(Manometric Respirometry Test, OECD No. 301 F)

<b>Ready biodegradability:</b>	Not readily biodegradable ≤ 1 %, 28 d (Manometric Respirometry Test, OECD No. 301 F)
<b>Bioaccumulative potential:</b>	No information available
<b>Mobility in soil:</b>	No information available
<b>Results of PBT and vPvB assessment:</b>	No information available
<b>Other adverse effects:</b>	No information available

### 13. DISPOSAL CONSIDERATIONS

<b>Waste treatment methods:</b>	Return to supplier or hand over to authorized disposal company
Waste from residues	Observe local/national regulations regarding waste disposal Incinerate in qualified installation with flue gas scrubbing Medicines should not be disposed of via wastewater

### 14. TRANSPORT INFORMATION

This product is not classified as a dangerous good.  
No special transport conditions are necessary unless required by other regulations.

### 15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

**Water hazard class :** Weakly hazardous for water

**FDA:** Calcitriol is an approved prescription medication

### 16. OTHER INFORMATION

Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.

**SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION**

#### TOXICOLOGY INFORMATION

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.