SAFETY DATA SHEET
Calcitriol capsules 0.25/0.5 MCG

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

Product Name: Calcitriol capsules
Chemical Name: 9,10-seco(5Z,7E)-5,7,10(19) cholestatriene-1α, 3β, 25-triol
Chemical formula: C_{27}H_{44}O_{3}
Molecular weight: 416.65
Company Name: Strides Arcolab Ltd, Opp to IIM, Bilekahalli, Arekare main Road, Bangalore-560076
How supplied: 0.25 & 0.5 mcg
Use: Pharmaceutical active substance for the treatment of hypocalcemia, management of hypoparathyroidism and metabolic bone disease.

2. COMPOSITION / INFORMATION ON INGREDIENTS

Characterization: Calcitriol and other inactive ingredients

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcitriol</td>
<td>32222-06-3</td>
<td>0.0000961 % (0.25 mcg) &amp; 0.000192 % (0.50 mcg)</td>
</tr>
<tr>
<td>Medium-chain triglycerides</td>
<td>85409-09-2</td>
<td>61.5 %</td>
</tr>
<tr>
<td>Gelatin</td>
<td>9000-70-8</td>
<td>27.3 %</td>
</tr>
<tr>
<td>Glycerol</td>
<td>56-81-5</td>
<td></td>
</tr>
</tbody>
</table>

3. HAZARDS IDENTIFICATION

Emergency overview: 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.

Primary Route(s) of Entry: Ingestion

Potential Health Effects:
- **Inhalation**: Not expected to be an inhalation hazard in final pharmaceutical form.
- **Eye Contact**: Not expected to be a hazard to the eye in final pharmaceutical form.
- **Skin Contact**: Not expected to be a hazard to the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation.
- **Ingestion**: May be harmful if ingested. Ingestion may cause weakness, nausea, vomiting, constipation and anorexia.
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Effects of Overexposure: 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.

Target Organs: Gastrointestinal tract

4. FIRST-AID MEASURES

Ingestion: If accidentally ingested contact a physician or a Poisons Information centre.

Skin Contact: Remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents

Eye Contact: Rinse immediately with tap water for 10 minutes - open eyelids forcibly.

Indication of any immediate medical attention and special treatment needed
Note to physician: Treat symptomatically

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Suitable extinguishing media - adapt extinguishing media to surrounding fire conditions

Specific hazards: No particular hazards known

Protection of fire-fighters: Precipitate gases/vapours/mists with water spray

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions : No special precautions required

Environmental Precautions : Do not allow to enter drains or waterways

Clean-up Methods : Take up mechanically and dispose of.

Decontamination Procedures: No specific decontamination or detoxification procedures have been identified for this product.

7. HANDLING AND STORAGE

General Requirements : Avoid breaking or crushing capsules.

Storage : Store at 20° to 25°C (68° to 77°F) [See USP controlled Room Temperatures] and protected from light.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold value air: IOEL (Internal Occupational Exposure Limit): 0.01 μg/m³ (Internal Occupational Exposure Limit, defined as 8-hour time-weighted average)

Respiratory protection: Respiratory protection not necessary during normal operations

Hand protection: Protective gloves (eg made of neoprene, nitrile or butyl rubber)

Eye protection: Safety glasses
9. PHYSICAL AND CHEMICAL PROPERTIES

Colour: Country-specific
Physical Form: Gelatin capsule soft
Other information: No information available

11. TOXICOLOGICAL INFORMATION

Acute toxicity: 
LD50 < 5 mg/kg (oral, rat) 
LD50 1.3 mg/kg (oral, mouse)

Local effects: 
Skin: non-irritant (rabbit) 
Skin: non-irritant (guinea pig) 
Eye: non-irritant (rabbit)

Sensitization: Non-sensitizing (guinea pig)

Chronic toxicity: 
Chronic overdosages 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.

Mutagenicity: Not mutagenic (Ames test)

Reproductive toxicity: Based on secondary effects (hypercalcemia), the substance may eventually lead to teratogenicity when overdosed

12. ECOLOGICAL INFORMATION

ECOTOXICITY: 
Barely toxic for algae (nominal concentration = 100 mg/l), test performed with water accommodated fractions (Scenedesmus (=Desmodesmus) subspicatus) 
EC50 (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) 
EC50 (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) 
LC50 (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)

Ready biodegradability: Not readily biodegradable
≤ 1 %, 28 d
(Manometric Respirometry Test, OECD No. 301 F)

Bioaccumulative potential: No information available

Mobility in soil: No information available
Results of PBT and vPvB assessment: No information available
Other adverse effects: No information available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods: 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.

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