SAFETY DATA SHEET-
ERGOCALCIFEROL CAPSULES USP [1.25mg] [50000IU VITAMIN D] [SOFT GELATIN]

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

Material Ergocalciferol, USP 50,000 IU Capsule

Company Name
Strides Arcolab Ltd,
Opposite to IIM,
Bilekahalli, Arekare main Road,
Bangalore-560076

2. COMPOSITION / INFORMATION ON INGREDIENTS

Active Ingredient	**CAS RN**
Ergocalciferol,	50-14-6
Inactive Ingredient	**CAS RN**
Glycerin	56-81-5
Soybean Oil	8001-22-7
FD &C Yellow No.5	1934-21-0
FD &C Blue 1	3844-45-9
Gelatin	9000-70-8

3. HAZARDS IDENTIFICATION

WARNING: This is a pharmaceutical product available without a prescription - use only as directed
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Fire and Explosion May emit Hydrogen chloride, nitrogen oxide and sulfur oxides under fire conditions.

4. FIRST-AID MEASURES

Ingestion
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In case of acute overdose by ingestion, seek immediate medical attention or contact the Poison Control Center for further instructions.

Inhalation Dust containing drag substance could be inhaled if capsules are crushed or broken. If dust is inhaled, remove to fresh air. Seek medical attention.

Skin Contact If contents of capsule comes in contact with skin and clothing, remove contaminated clothing and wash skin thoroughly with running water for at least 15 minutes. Use soap if available Seek medical attention if irritation develops.

Eye Contact In case of contact with contents of capsule, flush eyes with water for at least 15 minutes. Seek medical attention if irritation develops.

5. FIRE-FIGHTING MEASURES

If drug product handling produces dust, a risk assessment of the procedure should be performed.

Extinguishing Media Water spray, carbon dioxide or thy chemical powder.

Special Firefighting Procedures	As in any fire, use pressure demand self-contained breathing apparatus (SCBA) and protective clothing to prevent contact with skin and eyes. Use water spray to keep lire exposed contagious cool.
Hazardous Combustion Products	May emit Hydrogen chloride, nitrogen oxide and sulfur oxides under fire conditions.

6. ACCIDENTAL RELEASE MEASURES

If capsules arc crushed or broken, dust containing drug substance may be released. Minimize dust generation and accumulation. Do not breathe dust
Persona] protective equipment should be worn when cleaning up a spill
Wet-down all dusts and soak up contents of broken capsules with an sorbent material. Carefully collect material and place in a properly labeled waste container for disposal. Wash area of spill to remove from surfaces. Wash thoroughly after handling.

7. HANDLING AND STORAGE

HANDLING AND STORAGE PRECAUTIONS	Keep this and all drugs out of the reach of children.
WORK/HYGIENIC PRACTICES	If capsules arc crushed or broken, dust containing drug substance may be released. Avoid breathing dust and avoid contact with skin, eyes and clothing. Use local exhaust ventilation or respiratory protection for operations which generate dust. Wash thoroughly after handling.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

If drug product handling produces dust, a risk assessment of the procedure should be performed.

ENGINEERING CONTROLS

Exposure Controls	If capsules are crushed or broken, dust containing drug substance may be released. If dust is generated, local exhaust ventilation may be required.
SKIN PROTECTION	Avoid skin contact with contents of capsules. Impervious gloves should be worn.

PERSONAL PROTECTIVE EQUIPMENT

Eye/Face Protection	Avoid eye contact with contents of capsules. Wear safety glasses with side shields or goggles where risk of eye exposure exists.
Other Equipment or Procedures	None required for normal handling. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	
Colour	Green
Physical Form	oval shaped capsule.
Stability	This product is expected to be stable.
Conditions to Avoid.	Excessive heat, excessive exposure to light and air.

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11. TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS:

The safety of amounts of vitamin D (DRISDOL) in excess of 400 Iii per day, during pregnancy has not been established, Excessive vitamin D has been associated with fetal abnormalities including narrowing of the aorta, elfin face and mental retardation Therefore the use of vitamin D in excess of the recommended daily dose should be avoided during pregnancy.
May appear in the milk of nursing mothers, and may produce hypercalcemia in the newborn.
Can produce decline in average rate of growth, and produce increased mineralization of bones of infants and children (dwarfism), aches, stiffness, and weakness.

Animal Data	**Species**	**Route**	**Study**	**DS Result (mg/kg)**	**DP Result (mg/kg)**
	Guinea Pig	Oral	LD50	40	
	Dog	Oral	LD50	4	
	Rat	Oral	LD50	40	
			LD50	10	>10,000
	Mouse	oral	LD50	23.7	>10,000

Effects Of Repeated Doses
Oral deses of 0.66 mg/kg/d for 7 days produced cardiac and kidney changes, acute renal failure, changes in bladder weight and death in rats. Other effects reported in rats included changes in serum composition (RTECS).

Skin Effects
Not determined.

Eye Effects
Not determined.

Target Organ Effects
Adverse effects might occur in the following organ(s) following overexposure: bone marrow and formation of blood cells.

Sensitization
This product contains FD&C Yellow No.5 (tartrazine) which may cause allergic reactions (including bronchial asthma) in certain susceptible individuals.

Genetic Toxicity
Not determined.

Carcinogenicity
NTP: No IARC: No OSHA: No

Reproductive Effects
Effects in oral rat reproductive and developmental studies (22.5 to 45 mg/kg/day) effects produced included effects on extra embryonic structures (e.g. placenta, umbilical cord), effects on fetal growth. menstrual cycle changes effects on fertility, Stunted fetuses, musculoskeletal abnormalities, effects on the endocrine system, and effects on the newborn. In intramuscular (IM) rabbit studies (1.7 to 17 mg/kg/day) effects included cardiovascular abnormalities effects on newborn survival and growth, and abortions (high dose). In IM rat studies (35 mg/kg) effects included effects on the newborn and musculoskeletal system. At high doses in mice (200 mg/kg) effects on the central nervous system, and craniofacial and musculoskeletal effects were produced (information from RTECS).

12. ECOLOGICAL INFORMATION

Summary
No information is available

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13. DISPOSAL CONSIDERATIONS

Disposal Recommendations Dispose in accordance with local, state and federal regulation.

14. TRANSPORT INFORMATION

This product is not regulated for transportation by air, rail, highway or water.

15. REGULATORY INFORMATION

U.S. FEDERAL REGULATORY INFORMATION

This product does not contain any ingredients which are regulated on the U.S. EPA List of Toxic Chemicals (40 CFR 372), and is therefore not subject to release reporting under Section 313 of EPCRA.

16. OTHER INFORMATION

Not Applicable

DISCLAIMER OF EXPRESSED AND IMPLIED WARRANTIES

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.