ERGOCALCIFEROL CAPSULES, 1.25 mg Softgels (50,000 USP Units)
1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Orit Laboratories LLC
200 Fairfield Avenue
West Caldwell, NJ 07006

PRODUCT NAME: ERGOCALCIFEROL CAPSULES, 1.25 mg Softgels (50,000 USP Units)
CHEMICAL NAME: 9, 10-Secoergosta-5,7,10 (19),22-tetraen-3-ol, (3β,5Z,7E,22E)-;($C_{28}H_{44}O$)
SYNONYMS: Ergocalciferol, Vitamin D 2
CHEMICAL FAMILY: Vitamin Supplement

2. COMPOSITION/INFORMATION ON INGREDIENTS

ACTIVE INGREDIENT: Ergocalciferol
CAS NUMBER: 50-14-6

INACTIVE INGREDIENTS:

INGREDIENT	CAS NUMBER
Glycerin	56-81-5
Soybean Oil	8001-22-7
D & C Yellow No.10	8003-22-3
FD &C Blue No 1	3844-45-9

3. HAZARDS IDENTIFICATION

WARNING: This is a pharmaceutical product available without a prescription - use only as directed.

ERGOCALCIFEROL CAPSULES, 1.25 mg Softgels (50,000 USP Units)
is supplied as a green, oval shaped capsule.

POTENTIAL HEALTH EFFECTS:

INGESTION
Toxic if ingested in significant quantities.
May produce developmental effects in infants and children exposed to excessive amounts.

INHALATION
The effects of inhalation of liquid from burst capsules has not been determined. Effects may be presumed to be similar to those which can occur following ingestion.

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4. FIRST AID MEASURES

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

SKIN
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.

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

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

5. FIRE FIGHTING MEASURES

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

FIRE AND EXPLOSION HAZARDS
May emit hydrogen chloride, nitrogen oxide and sulfur oxides under fire conditions.

EXTINGUISHING MEDIA
Water spray, carbon dioxide or dry chemical powder.

FIRE FIGHTING INSTRUCTIONS
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 fire exposed containers cool.

6. ACCIDENTAL RELEASE MEASURES

If capsules are crushed or broken, dust containing drug substance may be released. Minimize dust generation and accumulation. Do not breathe dust. Personal protective equipment should be worn when cleaning up a spill [See Section 8]. Wet-down all dusts and soak up contents of broken capsules with an absorbent 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.

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7. HANDLING AND STORAGE
HANDLING AND STORAGE PRECAUTIONS
Keep this and all drugs out of the reach of children.
WORK/HYGIENIC PRACTICES
If capsules are 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
If capsules are crushed or broken, dust containing drug substance may be released. If dust is generated, local exhaust ventilation may be required.

EYE/FACE PROTECTION
Avoid eye contact with contents of capsules. Wear safety glasses with side shields or goggles where risk of eye exposure exists.

SKIN PROTECTION
Avoid skin contact with contents of capsules. Impervious gloves should be worn.
RESPIRATORY PROTECTION
None normally required. However, a respiratory program that meets OSHA's 29CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions, such as generation of dust, warrant respirator usage.

9. PHYSICAL AND CHEMICAL PROPERTIES
APPEARANCE
Green, oval shaped capsule.
The following data describes the active ingredient, Ergocalciferol.

BASIC PHYSICAL PROPERTIES
MELTING POINT (°C): 118-119
SOLUBILITY: Soluble in organic solvents; insoluble in water.
10. STABILITY AND REACTIVITY
STABILITY
Stable

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CONDITIONS TO AVOID
Excessive heat, excessive exposure to light and air.
INCOMPATIBLE MATERIALS (Powder)
Strong oxidizing agents, strong acids, strong bases.
HAZARDOUS DECOMPOSITION PRODUCTS
Toxic fumes of carbon monoxide and carbon dioxide.
HAZARDOUS POLYMERIZATION
Will not occur.

11. TOXICOLOGICAL INFORMATION

HUMAN CLINICAL DATA
POTENTIAL HEALTH EFFECTS:
The safety of amounts of **vitamin** D in excess of 400 IU 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.

ANIAMAL DATA
ACUTE EFFECTS (SINGLE DOSES)

Species	Route	Study	Result (mg/kg)
Guinea Pig	Oral	LD lo	40
Dog	Oral	LD lo	4
	Intraperitoneal		10
	Intravenous		5
	Intramuscular		5
Rat	Oral	LD lo	40
		LD 50	10
Mouse	Oral	LD 50	23.7

Effects produced in dogs included diarrhea, nausea, and vomiting.
EFFECTS OF REPEATED DOSES
Oral doses 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).
EYE AND SKIN IRRITATION: Not determined.

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GENOTOXIC EFFECTS: Not determined.

REPRODUCTIVE AND DEVELOPMENTAL 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).

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

MISCELLANEOUS TOXICOLOGICAL INFORMATION
Carcinogenicity - NTP: No IARC: No OSHA: No

12. ECOLOGICAL INFORMATION
None available.

13. DISPOSAL CONSIDERATIONS
Dispose in accordance with local, state and federal regulations.

14. TRANSPORT INFORMATION
Not regulated by USDOT as a hazardous material.
Not regulated by IATA as a dangerous good.

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, (SARA Title III).

16. OTHER INFORMATION

N/A = Not Applicable N/D = Not Determined = Approximately Equal To

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