

## Vitamin D3 100 A



## Section 1 – Chemical Product and Company Information

Product Name	Vitamin D3 100 A
Manufacturer's Name	Divis Laboratories Ltd.
Address	Divis Laboratories Limited Divi Towers, 7-1-77/E/1/303, Dharam Karan Road, Ameerpet, Hyderabad - 500 016 INDIA
Emergency contact number	0091-8922 245166
Emergency contact	Krishna Prasad

## Section 2 – Composition and Information on Ingredients

Chemical Name	CAS #	% by weight	EINECS #	Symbol	R-Phrases
Cholecalciferol	67-97-0	100'000 IU/g			
Gum Acacia	9000-01-5				
Sucrose	57-50-1				
Corn starch	9005-25-8				
Coconut oil	8001-31-8				
dl-alpha-Tocopherol	10191-41-0				
Sodium-Ascorbate	134-03-2				

## Section 3 – Hazards Identification

Physical / Chemical Hazards	Exposure: Inhalation, Ingestion, Skin contact, Eye contact
Human and Health Hazards	-NA-
Effects and Symptoms	-NA-
Eye	May cause eye irritation
Skin	May cause skin irritation
Symptoms of Exposure	May cause allergic reactions; May cause drying and/or irritation of the mucous membrane, may cause renal (kidney) system effects. Signs and symptoms may include urine retention, increase or decrease in urine production, painful urination and presence of blood in urine. May cause gastrointestinal effects, signs and symptoms include nausea,

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	vomiting, diarrhea, constipation, cramps and loss of appetite. May cause cardiovascular effects. Signs and symptoms may include increase or decrease in blood pressure, irregular heartbeat, chest pains and cardiac arrest. May cause respiratory effects. Signs and symptoms may include difficulty breathing, coughing, wheezing, irritation (inflammation) and respiratory arrest. May cause musculoskeletal effects. Signs and symptoms may include muscle weakness or pain and skeletal abnormalities.
Chronic effects	May increase blood calcium levels. May cause calcification (hardening) of soft tissue. May cause decalcification (softening) of bony tissue.
Target Organ Data	Eye, skin, kidneys, respiratory tract, cardiovascular system, gastrointestinal system, immune system, skeletal system.
Other Health Effects	Carcinogenicity : formulation not listed by NTP, IARC, or OSHA.
Additional health information	Reproductive toxicity of Cholecalciferol: may cause birth defects based on animal data. Since this material may affect the developing fetus, females planning to have a child and pregnant women should exercise caution regarding exposure. It is also advisable for nursing mothers to exercise caution regarding exposure. Conditions aggravated: hypersensitivity to this material. Kidney conditions and/ or impaired renal function. Cardiovascular conditions. Hypercalcemia. Respiratory system conditions. Individuals on digitalis therapy should avoid exposure to this material.

## Section 4 – First Aid Measures

First Aid Measures	
Eye Contact	Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower lids. Get medical attention if irritation occurs.
Skin Contact	Wash with soap and water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention if irritation develops.
Inhalation	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

## Section 5 – Fire-fighting Measures

Flash Point (liquid)	Not applicable
Hazardous Product of Combustion	Consider dust explosion or dust fire hazard. Actively cool fire-exposed containers with water spray or jet. Spontaneous ignition may occur when exposed to air.

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Fire Explosion Hazards	Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard.
Extinguishing Media	Water spray, carbon-dioxide, dry chemical powder or chemical foam.
Fire Fighting Instructions	Wear self-contained, breathing apparatus and protective clothing to prevent contact with skin and eyes. Wear appropriate NIOSH/MSHA approved respirator, chemical-resistant gloves, safety goggles, other protective clothing. Use only in a fume hood. Precipitate gases/ vapors/ mists with water spray.

### Section 6 – Accidental Release Measures

Large spill and leak	Vacuum or sweep up material and place into a suitable disposal container. Do not allow to enter drains or waterways.
Personal protection in case of large spill	Splash goggles, full suit, boots, gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

### Section 7 – Handling and Storage

Handling	Avoid breathing dust, vapor, mist or gas. Avoid contact with skin and eyes. Processing in closed systems, if possible superposed by inert gas (e.g. Nitrogen). Take precautionary measures against electrostatic charging. Avoid dust formation; high dust explosion hazard. Local exhaust ventilation necessary.
Storage	Do not store in direct sunlight. Store in tightly closed container. Store in a dry area. Cool storage.
Packing Materials	Use original container

### Section 8 – Exposure Controls / Personal Protection

Eye Protection	Wear chemical goggles.
Skin Protection	Wear appropriate protective clothing to prevent skin exposure.
Respiratory Protection	Wear a NIOSH/MSHA approved respirator.
Engineering Controls	Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit

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## Section 9 – Physical and Chemical Properties

Color	Yellowish white powder.
Odor	None
Physical State	Solid (powder)
Boiling Point/Melting point	Not applicable
Solubility	Satisfactory in cold water
Bulk density	~ 0.5 g/ cm <sup>3</sup>

## Section 10– Stability and Reactivity

Stability	The product is stable under conditions mentioned in chapter 7.
Conditions to avoid	Incompatible materials, light, exposure to air, exposure to moist air or water, warm temperatures.
Incompatibility	Strong oxidizing agents, strong acids, atmospheric oxygen.

## Section 11– Toxicological Information

Acute Toxicity	Acute over-dosage leads to nausea, vomiting, headache, weakness, strong thirst, abdominal pain and loss of appetite. LD 50: 15'000 mg/kg in Vitamin D3 100 A* (*calculation based on LD50 value for Vitamin D3 pure, Cholecalciferol, 5-50 mg/kg)
Chronic Toxicity	Chronic over-dosage may lead to formation of renal calculi, bone demineralization and formation of calcinations foci in lung and kidneys up to renal insufficiency.
Local effects	Skin: slightly irritating; eye: non-irritant.
Reproductive Effects	May lead to malformations at dose levels that cause maternal toxicity.
Note	Foodstuff, harmless at normal use; RDA (recommended daily allowance): 5 – 10 µg/d.

## Section 12– Ecological Information

Ready biodegradability	Readily biodegradable
Air pollution	Observe local/ national regulations

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**Section 13– Disposal Information**

Method of Disposal	Incinerate in qualified installation with flue gas scrubbing. Observe local/ national regulations regarding waste disposal.
Waste Classification	Not regulated under RCRA.

**Section 14– Transportation Information**

International Transport Regulations	
Proper Shipping Name	Vitamin D3 100 A
Note	Not regulated for transport under DOT, TDG, IATA, IMDG.
	Not classified as hazardous under DOT, IATA, IMDG.

**Section 15 – Regulatory Information**

US regulations	Ingredients are listed on the TSCA inventory. The USEPA has not established a reportable quantity (RQ) for releases of this material. State and local regulations vary and may impose additional reporting requirements.
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**Section 16 – Other Information**

Use	Additive for hard-shell capsules. For fortification of dry food products (flour, beverage powders, dry milk), for fortification of water-based foods.
Biological activity	1 IU (International Unit) of Vitamin D3 corresponds to the biological activity of 0.025 µg purest cholecalciferol.
<u>History</u>	
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Prepared By	Divi's Laboratories Limited