Safety Data Sheet

Divi's safety data sheet according to OSHA HCS

Product Name: Vitamin D_3 2 MIU/g

Version: 000 Revision date: 30.04.2020

SECTION 1: Identification

1.1 GHS Product identifier

Product name : Vitamin D_3 2 MIU/g

1.2 Recommended use of the chemical and restrictions on use

Used as Nutrient in food and dietary supplement preparation

1.3 Supplier's details : Divi's Laboratories Limited,
1-72/23(P)/Divis/303,
Divi towers, Cyber Hills, Gachibowli,
Hyderabad – 500 032, Telangana

E-mail: mail@divislaboratories.com

Website: www.divislabs.com

1.4 Emergency phone number: +91-8922-248944

SECTION: 2 Hazards Identification

2.1 Classification of the substance or mixture:

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Acute toxicity, Oral Category 4

Acute toxicity, Dermal Category 4

Acute toxicity, Inhalation Category 4

Skin sensitization Category 1B

Specific Target Organ Toxicity Repeated Exposure Category 1

2.2 GHS label elements,including precautionary statements

Signal word(s)

Danger

Hazard statement(s)

Harmful if swallowed

Harmful in contact with skin

Harmful if inhaled

May cause an allergic skin reaction

Causes damage to organs through prolonged or repeated exposure

Precautionary statement(s)

Prevention:

Avoid breathing mist/vapour/spray.

Wash hands thoroughly after handling.

Do not eat, drink or smoke when using this product.

Use only outdoors or in a well-ventilated area.

Contaminated work clothing should not be allowed out of the workplace.

Wear protective gloves/protective clothing

Response:

IF swallowed call a poison center/doctor/..if you feel unwell

IF ON SKIN: Wash with plenty of water

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Call a POISON CENTER/doctor/physician if you feel unwell.

Get medical advice/attention if you feel unwell

Specific treatment

Rinse mouth.

If skin irritation or rash occurs: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse

Storage

No data available

Disposal:

Dispose of contents/container in accordance with local/regional/national/international regulations

Hazard Pictograms:

2.3 Other hazards which do not result in classification

High risk of slipping due to leakage/spillage of product

SECTION 3: Composition/information on ingredients

3.1 Substances Material does not meet the criteria of a substance

3.2 Mixtures Refined soybean oil, DL-alpha-tocopherol, Vitamin D3(Cholecalciferol)

Substance Name	CAS No	Ec No	Content ratio W/W %	Classification according Regulation with 29 CFR 1910 (OSHA HCS)
Refined soybean oil	8001-22-7	232-274-4	90.0 - 95.0%	Not classified as hazardous substance
DI-alpha Tocopherol	10191-41-0	233-466-0	≤5.0%	Skin sensitization Category 1B
Vitamin D3 (Cholecalciferol)	67-97-0	200-673-2	≤5.0%	Acute Toxicity oral category: 2 Acute Toxicity Dermal categories.2 Acute Toxicity Inhalation category 2 Single Target Organ Toxicity Repeated Exposure 1

SECTION 4: First aid measures

4.1 Description of necessary first-aid measures

4.1.1 General information:

Immediately remove contaminated clothing. If adverse health develops seek medical attention.

On inhalation:

Keep patient calm, remove to fresh air, Seek medical attention.

On skin contact:

Wash with soap and water for at least 15 minutes' while removing contaminated clothing and shoes.

Get medical attention if irritation develops

On 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.

On ingestion:

DO NOT induce vomiting unless directed to do So by medical practitioner. Never give anything by mouth to an unconscious person. Get medical aid.

4.2 Most important symptoms/effects, acute and delayed

Symptoms/effects

Prolonged exposure may cause chronic effects

Excessive amounts of vitamin D in the body can cause calcium levels in the blood to rise. This can lead to a condition called hypercalcemia (too much calcium in your blood). Symptoms include:

Fatigue, loss of appetite, weight loss, excessive thirst, excessive urination, dehydration, constipation, irritability, nervousness, ringing in the ear (tinnitus), muscle weakness, nausea, vomiting, dizziness, confusion, disorientation, high blood pressure, heart arrhythmias

Taking extremely high doses of vitamin D3 for long periods may lead to excessive build-up in your body.

Vitamin D intoxication occurs when blood levels rise above 150 ng/ml (375 nmol/l). Because the vitamin is stored in body fat and released into the bloodstream slowly, the effects of toxicity may last for several months after you stop taking supplements

4.3 Indication of immediate medical attention and special treatment needed

Treatment: Symptomatic treatment (decontamination, vital functions).

Recommend that you reduce the amount of calcium in your diet temporarily. In some cases, corticosteroids or bisphosphonates may suppress the release of calcium from your bones.

SECTION 5: Firefighting measures

5.1 Extinguishing media:

Suitable extinguishing media:

Water spray, carbon dioxide, dry chemical powder or chemical foam.

Unsuitable extinguishing media:

Water jet

5.2 Special hazards arising from the substance or mixture:

Harmful vapors of substances mentioned can be released in case of fire.

Hazardous combustion products: Carbon oxides.

5.3 Advice for fire-fighters:

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.Fire-fighters should be equipped with self-contained breathing apparatus and turn-out gear

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel:

Protective equipment:

Splash goggles, full suit, Shoes, gloves. A self-contained breathing apparatus should be used to avoid Inhalation of the product. Ensure adequate ventilation.

Emergency procedures:

As an immediate precautionary measure, isolate spill or leak area for at least 50 meters (150feet) in all directions. Eliminate all ignition sources (no smoking, flares, sparks or flames in immediate area) Keep out of low areas. Keep unauthorized personnel away. Stay upwind. Ventilate closed spaces before entering.

6.1.2 For emergency responders:

Avoid contact with the skin, eyes and clothing.

Use with local exhaust ventilation.

Wear self-contained, breathing apparatus and protective Clothing to prevent contact with skin and eyes.

Wear a NIOSH-certified (or equivalent) organic vapour/particulate respirator.

Wear safety glasses with side-shields.

Wear chemical resistant protective gloves.

Wear protective clothing.

Eye wash fountains and safety showers must be easily accessible.

6.2 Environmental precautions

Do not empty into drains. Do not discharge into drains/surface waters/ground water.

6.3 Methods and material for containment and cleaning up

6.3.1 For containment:

For small amount: Rinse away with water.

For large amounts: Sweep/shovel up. Contain with liquid binding material and dispose of

For residues: Pick up with suitable appliance and dispose of.

Dispose of absorbed material in accordance with regulations

6.3.2 For cleaning up:

Cleaning operations should be carried out only while wearing breathing apparatus. Nonsparking tools should be used.

6.3.3 Other information:

Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

7.1.1 Protective measures

Advice on safe handling

Avoid breathing vapour, mist or gas. Avoid contact with skin and eyes

Take precautionary measures against electro-static charging. Local exhaust ventilation necessary. Provide suitable exhaust ventilation at the processing machines. Ensure thorough ventilation of stores and work areas.

Avoid contact with the skin, eyes and clothing

Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Prevent electrostatic charge – source of ignition should be kept well clear – fire extinguishers should be kept handy.

Avoid using tubes with push-in closures (when opened, the film of liquid trapped between tube and closure breaks and releases aerosols). Use a vortex mixer instead of inverting tubes. Wait 30 seconds after shaking a tube before opening. Use sealed safety cups and sealed rotors. Open cups inside a biosafety cabinet. Allow cups to sit prior to opening to allow aerosols to settle if no biosafety cabinet available

Do not empty into drains. Do not discharge into drains/surface waters/groundwater

7.1.2 Advice on general occupational hygiene

Wash hands thoroughly with soap and water thoroughly after handling. Take off contaminated clothing and wash it before reuse. Store work clothing separately. Hands and /or face should be washed before breaks and at the end of the shift.

Do not store in direct Sunlight, humidity, and especially to heat.

Do not breath mist. No eating, drinking, smoking or tobacco use at the place of work.

Handle in accordance with good industrial hygiene and safety practice.

Keep away from food, drink and animal feeding stuffs.

Safety shower and eye wash should be available close to work area

7.2 Conditions for safe storage, including any incompatibilities

The product should be stored at room temperature & dry conditions in the unopened original packaging. Contents should be used immediately after opening. Protect contents from the effects of light, atmospheric oxygen, strong oxidizing agents, reducing agents, strong acids, strong bases.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

8.1.1 Occupational exposure limit(s)

Substance name	CAS No	Occupational exposure Limits
Refined soybean oil	8001-22-7	No data available
DI-alpha-tocopherol	10191-41-0	OSHA- PEL:10 mg/m3(Total dust) TWA: 5 mg/m3(Respirable dust)
Vitamin D3 (cholecalciferol)	67-97-0	0.01 mg/m^3

8.2 Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials

8.3 Individual protection measures, such as Personal protective equipment (PPE)

Eye / Face protection:

Wear chemical safety goggles and/or a full-face Shield if there is potential for airborne dust exposures. Maintain eyewash fountain in work area.

Skin protection:

Shoes, gloves, lab coat, apron or coveralls, as appropriate, to protect skin contact.

Hand protection:

Wear Chemical resistant protective gloves, Suitable materials, plastic, and rubber

Body protection:

Wear impervious protective clothing, including shoes, gloves, lab coat, apron or coveralls, as appropriate, to protect skin contact.

Respiratory protection:

Wear respiratory protection if ventilation is inadequate. Wear a NIOSH-certified (or equivalent) organic vapour/particulate respirator. Suitable respiratory protection for higher concentrations or long-term effect. Breathing protection if breathable aerosols/dust are formed.

Thermal hazards:

No data available

SECTION 9. Physical and chemical properties and safety characteristics

9.1 Basic physical and chemical properties

Property	Remarks/Guidance
Appreance **Physical state**	Liquid
Colour	Yellow
Odour	None
Meltingpoint/freezingpoint	-10°C to 3°C (For melting)
Initial boiling point/boiling range	≥347 ° C (For soybean oil)
Flammability	No data available
Upper/lower flammability or explosive limits	No data available
Flash point	282°C (For soybean oil)
Auto-ignition temperature	No data available
Decomposition temperature	No data available
P^H	No data available
Kinematic viscosity	No data available
Solubility(ies)	Not soluble in water Soluble in oils and fats Soluble in lipophilic solvents
Partition- coefficient: n-Octanol/water	No data available
Vapour pressure	No data available
Density and/or relative density	No data available
Relative Vapour density	0.90-0.95 g/cm3 (25°C)
Particle Characteristics	No data available
Oxidising properties	Oxidizes in presence of oxygen when kept in open conditions
Viscosity Dynamic	≤100 Cp at ambient temperature.

9.2 Other information

No data available

SECTION 10: Stability and Reactivity

10.1 Reactivity

No hazardous reactions if stored and handled as prescribed/indicated.

10.2 Chemical stability

No hazardous reactions when stored and handled according to instructions

10.3 Possibility of hazardous reactions

No hazardous reactions when stored and handled according to instructions

10.4 Conditions to avoid

Avoid all sources of ignition: heat, sparks, and open flame.

10.5 Incompatible materials

Atmospheric oxygen, Strong oxidizing agents, reducing agents, strong acids, strong bases

10.6 Hazardous decomposition products

No hazardous decomposition products if stored and handled as prescribed /indicated.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

ATE of Mixture

LD 50 Value Oral	: 840 mg/kg (Rat)
LD50 Value Dermal	: 1220 mg/kg (Rat)
LD50 Value inhalation	: 2.6 mg/l (Rat)

Information on: Vitamin D3

Oral LD50 Rat 42 mg/kg

The result of this study falls within category 3 for acute toxicity if the LD50 is based on the lower end of the 95% confidence limits in males (i.e. 268-484 mg/kg bw). The study thus confirms the existing classification in category 3. However, the LD50 values set in the study with Wistar rats were lower and it is not possible to conclude if the higher toxicity in this study was due to a higher purity of the test substance or if it was related to the type of strain used. The study report describing the study in Wistar rats does not include a vitamin D3 activity analysis but pathology confirmed hypercalcinosis at the lethal dose which at least supports that the substance tested indeed was cholecalciferol. The LD50 set in Wistar rats is 35 (with 95% confidence limits of 24 – 53 mg/kg bw) in males and 47 mg/kg bw (with 95% confidence limits of 28 – 79 mg/kg bw) in females. Taking into consideration the acute toxicity data presented here, classification in acute toxicity category 2, H300 (fatal if swallowed) is proposed based on the LD50 of 35 mg/kg bw set in the study using Wistar rats

Dermal LD50 Rat 61 mg/kg

The existing classification of cholecalciferol as Acute Tox. 3* (H311) in Annex VI of CLP is a minimum classification the criteria for classification in category 1 could be considered fulfilled if the lower confidence limit for the LD50 set in male rats is used as the ATE. However, the LD50 values set for both male and female rats

fall within the range for category 2. Moreover, effects were similar to those observed in the acute oral and inhalation toxicity studies and dermal toxicity rarely exceeds oral toxicity and toxicity via inhalation. Therefore, the acute dermal toxicity of cholecalciferol is proposed to fulfil criteria for classification in category 2.

Inhalation LC 50 Rat 0.13- 0.38 mg/l

Under the conditions of the acute inhalation study available, the LC50 after a 4-hour exposure and a 35-day observation period was estimated to be in the range of 130 – 380 mg/m3 (0.13-0.4 mg/L).

Post-exposure observations of clinical symptoms showed systemic effects indicative of effects on the mood, motor activity and coordination, posture, muscle tone and the autonomic nervous system. However, since mortality occurred in some of the animals at the same dose levels, these symptoms are considered to reflect general toxicity rather than a specific effect on the nervous system. Pathology findings considered to be treatment related include:

Male rats: pale kidneys with roughened surface, white spots and areas in the myocardium, white area in the stomach and red spots on the lungs. Female rats: pale kidneys with roughened surface, white spots and areas in the myocardium, white area in the stomach and red spots on the lungs.

The LC50 is within the range of 0.13-0.15 mg/l for males and 0.14 to 0.4 mg/l for females. These values fall within the range for classification in category 2, i.e. 0.05 < ATE ≤ 0.5 mg/l (dust and mist).

Skin corrosion/ irritation

Mixture is not a skin irritant. The product has not been tested. The statement has been derived from the properties of the individual components.

Serious eye damage/irritation

Mixture is not an eye irritant. The product has not been tested. The statement has been derived from the properties of the individual components.

Respiratory or skin sensitisation

May cause skin sensitization. The product has not been tested. The statement has been derived from the properties of the individual components

Information on DL alpha Tocopherol

Skin sensitization:

Skin sensitisation potential of D, L-alpha-tocopherol was investigated in the Open Epicutaneous Test (OET), which was carried out in the albino Guinea pig (OECD guideline 406, non-GLP; Csato, 1997). During the induction phase of sensitisation, the test article was applied epicutaneously onto the skin of the test animals 5 days a week for 4 consecutive weeks. The test article induced slight to strong irritant skin reactions in the experimental animals after repeated application during the induction treatment. Considering the above experimental data, it can be concluded that topically applied D, L-alpha-tocopherol revealed a skin sensitizing potential at higher concentrations (> 3%) in Guinea pigs and in the mouse LLNA.However, cutaneous exposure to D, L-alpha-tocopherol at lower (non-irritating) concentrations (< = 1 % in Guines pigs and < = 3% in mice) did not result in sensitisation responses, and accordingly, is unlikely to give rise to skin sensitisation in man

Germ cell mutagenicity

Mixture is not a mutagen**.** The product has not been tested. The statement has been derived from the properties of the individual components.

Information on Vitamin D3

An additional classification to current classification as Mutagenic category 2, H341 is warranted.

Nevertheless, there is no concern for germ cell mutagenicity at exposure levels restoring normal vitamin D levels (i.e. exposure in the dietary supplementation range).

Carcinogenicity

Mixture is not carcinogenic. The product has not been tested. The statement has been derived from the properties of the individual components

Information on Vitamin D3

The data available to assess the intrinsic carcinogenic potential of cholecalciferol is limited. The human data reported is restricted to doses in the range used for vitamin supplementation and the animal data is limited to studies performed with a duration only representing approximately 25% of the lifespan of a rat. Nevertheless, phaeochromocytomas was observed already after 26 weeks and there is thus considered to be evidence from animal studies that high doses of cholecalciferol could be carcinogenic in humans. Therefore, classification in category 2 is proposed. Specific concentration limits are not considered warranted.

Reproductive Toxicity

Mixture is not a reproductive effector. The product has not been tested. The statement has been derived from the properties of the individual components

Information on Vitamin D3

Due to limitations in the data on reproductive toxicity, i.e. lack of thorough investigations of all parameters required for an accurate assessment of effects on fertility and developmental toxicity and/or deficiencies with respect to methodology and reporting, data is not considered sufficient to assess if the intrinsic properties of cholecalciferol fulfil criteria for classification. Therefore, no classification with respect to fertility, teratogenicity or lactation is proposed.

STOT-Single Exposure

No data available. The product has not been tested

Information on Vitamin D3

No signs of respiratory irritation (estimated as clinical signs and effect on respiratory frequency), no dose related increase in lymphocytes was determined in lung tissue and no narcotic effects were observed during exposure to cholecalciferol. Therefore, cholecalciferol is not considered to meet criteria for classification STOT SE.

STOT-repeated Exposure

Causes damage to organs through prolonged or repeated exposure at higher concentrations. The product has not been tested. The statement has been derived from the properties of the individual components.

Information on: Vitamin D3

Causes damage to organs through prolonged or repeated exposure

The CLP guidance value for classification as STOT RE in category 1 after a 90-day repeated-dose study is C ≤ 10 mg/kg bw/day (oral, rat). In the studies available for this assessment, effects observed and considered relevant for this category include progressive hypercalcemia with tissue mineralisation in several organs and proliferative adrenal pathology since these were observed already at doses of 0.06 mg/kg bw/day and 0.3 mg/kg bw/day, respectively, in the 90-day rat study (Table 10.9.d). The effects are consistent between studies and indicate an impaired organ function at doses that are well within the guidance value set in the CLP regulation for a 90-day study in rats. The existing classification as STOT RE 1 is therefore confirmed

Aspiration Hazard:

No data available

11.2 Information on the likely routes of exposure

Inhalation:

Inhalation of mist may cause respiratory irritation. Prolonged inhalation may be harmful.

Skin contact:

No adverse effects due to skin contact are expected.

Eye contact:

Mist spill in the eyes will cause irritation.

Ingestion

Expected to be a low ingestion hazard

11.3 Symptoms related to the physical, chemical and toxicological characteristics

Over exposure may result in Nausea, vomiting, and poor appetite, Stomach pain, constipation, or diarrhea

11.4 Delayed and immediate effects and also chronic effects from short term and long term exposure.

Long-term complications of untreated hypervitaminosis D include:

Hypercalcemia - Early symptoms of hypercalcemia, include nausea and vomiting, weakness, headache, somnolence, dry mouth, constipation, metallic taste, muscle pain and bone pain. Late symptoms and signs of hypercalcemia, include polyuria, polydipsia, anorexia, weight loss, nocturia, conjunctivitis, pancreatitis, photophobia, rhinorrhoea, pruritis, hyperthermia, decreased libido, elevated BUN, albuminuria, hypercholesterolemia, elevated ALT (SGPT) and AST (SGOT), ectopic calcification, nephrocalcinosis, hypertension and cardiac arrhythmias.

SECTION 12: Ecological information

12.1 Toxicity:

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment

12.2 Persistence and degradability:

No data is available on the degradability of this product

Information on Vitamin D3

Not easily biodegradable

12.3 Bio accumulative potential:

No data available

12.4 Mobility in soil:

No data available

12.5 Other adverse effects:

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods.

Contact a licensed professional waste disposal service to Dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an after burner and scrubber. Observe all federal, state, and local environmental regulations

SECTION 14: Transport information

Regulation		Land transport (DOT)	Sea transport (IMDG)	Air transport (ICAO/IATA)
14.1	**UN No.**	Not regulated as dangerous goods	Not regulated as dangerous goods	Not regulated as dangerous goods
14.2	**UN Proper shipping name**			
14.3	**Transport hazardclass(es)**			
	Hazard label(s)			
14.4	**Packing group**			
14.5	**Envirommental hazards**	-----	-----	-----

14.6 Special precautions for user

None

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

US regulations

TSCA section 12(b) Export notification (40 CFR 707, subpt. D): Not Regulated

CERCLA Hazardous substances list (40 CFR 302.4): Not listed

SARA 304 Emergency release notification.: Not Regulated

SECTION 16: Other information

16.1 Preparation information

Product code	: II/Vitamin D_3 2 MIU/g/02
Version	: 000
Effective Date	: 30.04.2020
Date of previous issue	: -----
Prepared by	: Divi's Laboratories Limited

16.2 Abbreviations and acronyms:

DOT: Department of Transportation

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System

EC No: European Community No.

ACGIH: American conference of governmental industrial hygienist

OSHA: Occupational safety & health administration

TLV: Threshold limit value

TWA: Time weighted average

PEL: Permissible exposure limit

STOT: Specific target organ toxicity

CAS: Chemical Abstracts Service (division of the American Chemical Society)

TSCA: Toxic Substance control act

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

16.3 Key literature references and sources for data

https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/5882

https://static.usp.org/pdf/EN/referenceStandards/msds/1131009.pdf

https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/132309

16.4 Further information:

Training advice: Consult your supervisor or local safety & health Professional for required training appropriate for the safe handling, use of protective equipment, and Emergency response for this material.

Notice to Reader

NOTICE: This Safety Data Sheet is based upon data considered to be accurate at the time of preparation. Despite our efforts, it may not be up to date or applicable to the circumstances of any particular case. We are not responsible for any damage or injury resulting from abnormal use, from any failure to follow appropriate practices or from hazards inherent in the nature of the product

END OF THE SAFETY DATA SHEET