# **Safety Data Sheet**

Divi's safety data sheet according to OSHA HCS

Product Name: Vitamin D2 100 SD

Version: 000 Revision date: 08.05.2020

# **SECTION 1: Identification**

1.1 GHS Product identifier

Product name: Vitamin D2 100 SD

1.2 Recommended use of the chemical and restrictions on use

Used as Nutrient in dietary supplement Preparations.

1.3 Supplier's details

Name Divi's Laboratories Limited

**Address** 1-72/23(P)/Divi's/303,

Divi towers, Cyber Hills,

Gachibowli, Hyderabad - 500 032,

Telangana, India.

E-mail mail@divislaboratories.com

Web site: 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)

Skin sensitization. Category 1B

2.2 GHS label elements, including precautionary statements

Signal word(s)

Warning

Hazard statement(s)

May cause an allergic skin reaction

Precautionary statement(s)

Prevention

Avoid breathing dust/vapours

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

Wear protective gloves.

Response

IF ON SKIN: Wash with plenty of water.

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

Specific treatment

Take off contaminated clothing and wash it before reuse.

Storage

No data available

**Disposal** 

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



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# Pictogram(s)



# 2.3 Other hazards which do not result in classification

May form combustible dust concentration in air.

# **SECTION 3:** Composition/information on ingredients

3.1 Substances: Not Applicable

**Mixtures:** Modified starch, Sucrose, RBD Sunflower oil Sodium ascorbate, DL-alpha-tocopherol, Vitamin D2 (Ergocalciferol),

| Substance Name                 | CAS No     | Ec No.    | Content ratio | Classification according Regulation<br>(29 CFR 1910 (OSHA HCS)  |  |
|--------------------------------|------------|-----------|---------------|---|--|
| Modified starch                | 66829-29-6 | -         | 70.0 - 80.0   | Not classified as hazardous substance   |  |
| Sucrose                        | 57-50-1    | 200-334-9 | 10.0 - 20.0   | Not classified as hazardous substance   |  |
| RBD Sunflower oil              | 8001-21-6  | 232-273-9 | ≤ 5.0         | Not classified as hazardous substance   |  |
| Sodium ascorbate               | 134-03-2   | 205-126-1 | ≤ 5.0         | Not classified as hazardous substance   |  |
| DI-alpha tocopherol            | 10191-41-0 | 233-466-0 | ≤ 5.0         | Skin sensitization. Category 1B   |  |
| Silicon dioxide                | 7631-86-9  | 231-545-4 | ≤ 1.0         | Not classified as hazardous substance   |  |
| Vitamin D2<br>(Ergocalciferol) | 50-14-6    | 200-014-9 | ≤ 0.25 %      | Acute Toxicity Oral Category: 2 Acute Toxicity Dermal categories.3 Acute Toxicity inhalation category 2 Single Target Organ Toxicity Repeated Exposure Category 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 effects develop, seek medical attention

#### On inhalation

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

### 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

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# 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

Rinse mouth and then drink plenty of water. DO NOT induce vomiting unless directed to do so by medical practitioner. Never induce vomiting or give anything by mouth if the victim is unconscious or having Convulsions. Seek medical attention if necessary.

# 4.2 Most important symptoms/effects, acute and delayed

#### Symptoms/effects:

Nausea, vomiting and diarrhoea, weight loss, irritability, weakness, fatigue, lassitude, and headache.

# 4.3 Indication of immediate medical attention and special treatment needed

Treatment: Symptomatic treatment (decontamination, vital functions)

The treatment of hypervitaminosis D with hypercalcemia consists in immediate withdrawal of the vitamin, a low calcium diet, generous intake of fluids, along with symptomatic and supportive treatment. Hypercalcemia crisis with dehydration, stupor, coma, and azotemia requires more vigorous treatment. The first step should be hydration of the patient. Intravenous saline may quickly and significantly increase urinary calcium excretion. A loop diuretic (furosemide or ethacrynic acid) may be given with the saline infusion to further increase renal calcium excretion. Other reported therapeutic measures include dialysis or the administration of citrates, sulfates, phosphates, corticosteroids, EDTA (ethylenediaminetetraacetic acid), and mithramycin.

# **SECTION 5:** Fire fighting 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:

#### Gum acacia

As with all carbohydrate materials, a dust explosion hazard exists if the dust concentration in air is high. Spray-dried gum acacia is a St class 1 powder, with Kst = 63 bar m/s.

#### For starch/ air mixtures

Starch is a class St1 dust at normal moisture level:

Minimum Ignition Temperature (MIE): >30 mJ at normal moisture level

Pmax 9.5 Bar

Kst 170 bar.m/s

Layer Ignition Temperature: >450 deg C

Autoignition Temperature: 170 deg C (above this temperature starch will self-heat)

**Dust Explosion Hazard Class 1** 



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Harmful vapors of substances mentioned can be released in case of fire Combustible. Finely dispersed particles form explosive mixtures in air. 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, and 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/groundwater

# 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 dust binding material and dispose of

For residues: Contain with dust binding material and dispose of. Pick up with suitable appliance and dispose of absorbed material in accordance with regulations.



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# 6.3.2 For cleaning up:

Cleaning operations should carry 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 Advice on safe handling

Avoid breathing dust, vapour, mist or gas. Avoid contact with skin and eyes. Take precautionary measures against electro-static charging. Avoid dust formation. 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 dust formation. Provide exhaust ventilation if dust is formed. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. 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 after handling.

Take off contaminated clothing and wash it before reuse.

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

No eating, drinking, smoking or tobacco use at the place of work.

Hands and /or face should be washed before breaks and at the end of the shift.

Store work clothing separately.

Handle in accordance with good industrial hygiene and safety practice.

Keep away from food, drink and animal feeding stuffs.

Safety shower and eyewash should be available close to work area.

# 7.2 Condition's for safe storage, including any incompatibilities

Avoid dust formation. 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 and strong bases.



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# SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

# 8.1.1 Occupational exposure limit(s)

| Substance Name              | CAS No     | Occupational exposure limit(s)  |  |
|-----------------------------|------------|---|--|
| Modified starch             | 66829-29-6 | No data available   |  |
| Sucrose                     | 57-50-1    | OSHA PEL TWA:15 mg/m3 (Total dust);<br>TWA:5 mg/m3 (Respirable fraction);<br>ACGIH TLV-TWA:10 mg/m3 |  |
|                             |            | NIOSH REL-TWA:10 mg/m3  |  |
| RBD Sunflower oil           | 8001-21-6  | No data available   |  |
| Sodium ascorbate            | 134-03-2   | No data available   |  |
| Di-alpha tocopherol         | 10191-41-0 | TWA 10 mg/m3 (Canada)<br>OEL PEL 5 mg/m3 (US)   |  |
| Silicon dioxide             | 7631-86-9  | No data available   |  |
| Vitamin D2 (Ergocalciferol) | 50-14-6    | No data available   |  |

#### 8.2 Appropriate engineering controls:

### **Dust Control Measures**

The dust-containing systems (ducts and dust collectors) are designed in a manner (i.e., no leaking) that fugitive dusts are not allowed to accumulate in the work area.

The facility has a housekeeping program with regular cleaning frequencies established for floors and horizontal surfaces, such as ducts, pipes, hoods, ledges, and beams, to minimize dust accumulations within operating areas of the facility.

The working surfaces are designed in a manner to minimize dust accumulation and facilitate cleaning.

#### **Ignition Control Measures**

Electrically-powered cleaning devices such as vacuum cleaners, and electrical equipment are approved for the hazard classification for Class II locations.

The facility has an ignition control program, such as grounding and bonding and other methods, for dissipating any electrostatic charge that could be generated while transporting the dust through the ductwork. Duct systems, dust collectors, and dust-producing machinery are bonded and grounded to minimize accumulation of static electrical charge.

#### **Prevention Measures**

The facility has separator devices to remove foreign materials capable of igniting combustible dusts.

SDSs for the chemicals which could become combustible dust under normal operations are available to employees.

Employees are trained on the explosion hazards of combustible dusts.

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#### **Protection Measures**

The facility has an emergency action plan.

Dust collectors are not located inside of buildings. (Some exceptions) Rooms, buildings, or other enclosures (dust collectors) have explosion relief venting distributed over the exterior wall of buildings and enclosures.

Explosion venting is directed to a safe location away from employees.

The facility has isolation devices to prevent deflagration propagation between pieces of equipment connected by ductwork.

The dust collector systems have spark detection and explosion/ deflagration suppression systems.

Emergency exit routes are maintained properly

# 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:**

Body protection must be chosen depending on activity and possible exposure, e.g. head Protection, apron, protective Shoes, chemical-protection suit.

# 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: None

# SECTION 9: Physical and chemical properties and safety characteristics

# 9.1 Basic physical and chemical properties

| Property                                     | Remarks / Guidance     |  |  |
|--|------------------------|--|--|
| Physical state                               | Solid- free flowing    |  |  |
| Colour                                       | Off white to yellowish |  |  |
| Odour  | None                   |  |  |
| Meltingpoint/freezingpoint                   | No data available      |  |  |
| Initial boiling point/boiling range          | No data available      |  |  |
| Flammability                                 | No data available      |  |  |
| Upper/lower flammability or explosive limits | No data available      |  |  |



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| Flash point                             | No data available                    |  |  |
|---|--------------------------------------|--|--|
| Auto-ignition temperature               | Not determined                       |  |  |
| Decomposition temperature               | Not determined                       |  |  |
| pH                                      | 4.0 to 5.0 (10% dispersion in water) |  |  |
| Kinematic viscosity                     | No data available                    |  |  |
| Solubility(ies)                         | Dispersible in water                 |  |  |
| Partition- coefficient: n-Octanol/water | Not determined                       |  |  |
| Vapour pressure                         | No data available                    |  |  |
| Density and/or relative density         | 0.55 - 0.65 g/cm3                    |  |  |
| Relative Vapour density                 | No data available                    |  |  |
| Particle Characteristics                | No data available                    |  |  |

# 9.2 Data relevant with regard to physical hazard classes (Supplemental)

Corrosion to metals: Corrosive effects to metal are not anticipated

# **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 dust formation and electro-static charge. Avoid all sources of ignition exposure to heat, light & Moist air

# 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. Decomposition in abnormal conditions forms Carbon oxides.

# **SECTION 11: Toxicological information**

# 11.1 Information on toxicological effects

#### Acute toxicity:

ATE mix Oral: > 4000 mg/kg (Rat)

# Information on: Vitamin D<sub>2</sub>

Dermal LD50 Rat 61 mg/kg

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# Oral LD50 Rat 10 mg/kg. Skin corrosion/ irritation

Classification not possible. The product has not been tested. The statement has been derived from the properties of the individual components

# Serious eye damage/irritation

Classification not possible. 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 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

#### Carcinogenicity

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

# **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

### STOT-Single Exposure

No data available

#### STOT-repeated Exposure:

May cause damage to kidney and bones on repeated exposure. The product has not been tested. The statement has been derived from the properties of the individual components

Information on: Vitamin D<sub>2</sub>

Causes damage to organs (kidney, bone) through prolonged or repeated exposure.

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Aspiration Hazard

No data available

Other information

No data available

#### 11.2 Information on the likely routes of exposure

#### Inhalation:

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

#### Skin contact:

No adverse effects due to skin contact are expected.

# Eye contact:

Dust 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

Vitamin D analogs: Hypercalcemia. Gastrointestinal disturbances. Dry mouth. Metallic taste. Bone or muscle pain. Tiredness. Weakness. Headache. Confusion. Irregular heartbeat.

# 11.4 Delayed and immediate effects and chronic effects from short term and long-term Exposure

No data available

# **SECTION 12: Ecological information**

# 12.1 Toxicity:

No data available

# 12.2 Persistence and degradability:

No data available

# 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 Disposal 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.



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# **SECTION 14: Transport information**

|      | Regulation Transport       | Land transport<br>( US DOT) | Sea transport<br>(IMDG)            | Air transport (IATA/ICAO)          |
|------|----------------------------|-----------------------------|------------------------------------|------------------------------------|
| 14.1 | UN No.                     |                             |                                    |                                    |
| 14.2 | UN Proper Shipping name    |                             |                                    |                                    |
| 14.3 | Transport hazard class(es) | Not regulated as            | Not regulated as a dangerous goods | Not regulated as a dangerous goods |
|      | Hazard label(s)            | a dangerous<br>goods        |                                    |                                    |
| 14.4 | Packing group              |                             |                                    |                                    |
| 14.5 | Environmental 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:

No data available

# **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 D2100 SD/02

Version : 000

Effective Date : 08.05.2020

Date of previous issue: -----

Prepared by : Divi's Laboratories Limited

# 16.2 Abbreviations and acronyms:

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System

CLP: Regulation on Classification, labeling and packing of substance& mixture

EC No: European Community No.

ACGIH: American conference of governmental industrial hygienist

OSHA: Occupational safety & health administration



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TLV: Threshold limit value
TWA: Time weighted average

**UN: United nation** 

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://static.usp.org/pdf/EN/referenceStandards/msds/1239005.pdf

https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/36576 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 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.