



# Safety Data Sheet

Divi's safety data sheet according to OSHA HCS

Product Name: Lycopene 10% LF

Version: 000

Revision date: 05.05.2020

## **SECTION 1: Identification.**

### **1.1 GHS Product identifier**

**Product name** : Lycopene 10% LF

### **1.2 Recommended use of the chemical and restrictions on use**

Used for colorization and fortification of food and dietary supplement applications..

### **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](mailto:mail@divislaboratories.com)

**Web site:** [www.divislabs.com](http://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 mist/vapours/spray.

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:**

Not applicable

**Disposal:**

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



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## 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: Not applicable

### 3.2 Mixtures: Refined corn oil , Lycopene, DL alpha tocopherol.

Substance Name	CAS No	Ec No	Content ratio W/W %	Classification according Regulation (29 CFR 1910 (OSHA HCS)
Refined corn oil	8001-30-7	232-281-2	80.0 - 90.0%	Not classified as a hazardous substance
Lycopene	502-65-8	207-949-1	10.0 - 12.5%	Not classified as a hazardous substance
DL-alpha tocopherol	10191-41-0	233-466-0	≤ 3.0%	Skin sensitization, Category 1B

## 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, move 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:

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:

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

### 4.2 Most important symptoms/effects, acute and delayed

#### Symptoms/effects:

May cause skin sensitization



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## 4.3 Indication of immediate medical attention and special treatment needed

### Treatment:

Symptomatic treatment (decontamination, vital functions). No known specific antidote.

## **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:

Will be easily ignited by heat, sparks or flames at ambient temperatures. Vapours will form explosive mixtures with air. Containers may explode when heated.

#### 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.



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## 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:

Absorb with inert, absorbent material. Sweep up. Nonsparking tools should be used to collect material and place it in loosely-covered metal or plastic containers for later Spills & Disposal

For residues: Pick up with suitable appliance and 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. Clean spillage area thoroughly with plenty of water.

### 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:

Do not breathe vapour. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Take precautionary measures against static discharges.

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.

Other safety devices include safety centrifuges with automatic locking mechanisms or solid lids, safety centrifuge cups, safety blenders, safety sonicators. Vacuum line trap and filter systems are used to protect the vacuum system from aerosols.

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

#### 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 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 eye wash should be available close to work area.



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

The product should be stored at dry and cool place 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 corn oil	8001-30-7	No data available
Lycopene	502-65-8	No data available
DL-alpha tocopherol	10191-41-0	TWA : 10 mg/m3 (Canada) OEL PEL: 5 mg/m3 (US)

### 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. 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

#### Body protection:

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

#### Respiratory protection:

Breathing protection if breathable aerosols are formed. Wear a NIOSH –certified (or equivalent) Particulate.



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## Thermal hazards:

No data available

## **SECTION 9. Physical and chemical properties and safety characteristics**

### **9.1 Basic physical and chemical properties**

Property	Remarks / Guidance
Physical state	Liquid - Suspension
Colour	Red color
Odour	No data available
Meltingpoint/freezingpoint	-10°C to -16°C (For melting)
Initial boiling point/boiling range	402.8°C at atmosphere (For corn oil)
Flammability	No data available
Upper/lower flammability or explosive limits	No data available
Flash point	≥250°C (For Corn oil)
Auto-ignition temperature	Not determined
Decomposition temperature	Not determined
pH	No data available
Kinematic viscosity	No data available
Solubility(ies)	Not soluble in water Sparingly soluble in oils and fats Soluble in lipophilic solvents
Partition- coefficient: n-Octanol/water	Not determined
Vapour pressure	No data available
Density and/or relative density	0.90 – 0.95 g/cm <sup>3</sup> (25°C)
Relative Vapour density	No data available
Particle Characteristics	No data available
Oxidising properties	Oxidizes in presence of oxygen when kept in open conditions.

### **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



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## 10.3 Possibility of hazardous reactions:

No hazardous reactions when stored and handled according to instructions

## 10.4 Conditions to avoid:

Avoid formation of 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:** Classification criteria are not met

ATE mix Oral Rat > 5000mg/Kg

#### Information on Lycopene

**Oral** LD50 Rat > 3000 mg/kg

The NOAEL value from a 90-day oral toxicity study with lycopene extracted from B.trispora was 600 mg/kg bw per day.

When rats were fed 1 g/(kg · d) of crystalline lycopene, there were no adverse clinical signs or histopathology. Furthermore, up to 3 g/(kg · d) of formulated lycopene exhibited no effects on body weight, hematology, blood chemistry, ophthalmologic variables, or histology in rats (1,5). When rats were fed varying doses [0 to 616 mg/(kg · d)] of lycopene derived by the fungus Blakeslea trispora, there were no adverse effects on clinical or neurological observations, motor activity, consumption, clinical chemistry, or hematology.

#### **Skin corrosion/ Irritation:**

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

#### Information on Lycopene

No skin reactions were observed. Orange staining of the skin was observed in all test animals during the whole test period. The test substance is not irritating to the skin of rabbits.

#### **Serious eye damage/irritation:**

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

#### **Respiratory or skin sensitisation:**

Mixture 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:



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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 Guinea pigs and < = 3% in mice) did not result in sensitisation responses, and accordingly, is unlikely to give rise to skin sensitisation in man

## Information on Lycopene

Guinea pig maximization test

Result: Not sensitizing

## **Germ cell mutagenicity:**

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

## Information on Lycopene:

The studies followed OECD test guidelines 471, 473, 474, 476 or 486. The in vitro studies included tests for gene. mutation in bacteria (Salmonella typhimurium, Escherichia coli), the in vivo studies included a test for micronucleus formation in mouse peripheral blood, tests for DNA damage in human lymphocytes and a test for spontaneous mutation in LacZ mouse DNA. All the results were negative, which means that lycopene was not genotoxic, based on these tests.

## **Carcinogenicity:**

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

## Information on Lycopene:

In a most recent AFC opinion two long term studies in rats with synthetic lycopene are described (51 and 104 weeks respectively).

Additional long-term studies with oral administration of synthetic lycopene can be found in the AFC opinion which describes studies revealing

A NOAEL of 50mg lycopene/Kg bw/day in a one-year rat study

A NOAEL of 50mg lycopene/Kg bw/day (the highest dose level tested) in a two-year rat carcinogenicity study.

## **Reproductive Toxicity:**

Mixture is not considered to be a reproductive toxin. The product has not been tested. The statement has been derived from the properties of the individual components





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## Information on Lycopene:

study on rats and rabbits in which 0, 0.5, 1.5, or 3 g/(kg · d) of formulated lycopene was given during gestation. There was no effect of lycopene intake on body weight, necropsy findings, foetal development, or skeletal morphology of the offspring. When pregnant rats were given 1 g/(kg · d) of crystalline lycopene for 200 d, there was evidence of pigment accumulation in the liver; however, there were no signs of histopathology. Furthermore, there was no effect on the number of aborted pregnancies or duration of gestation and no evidence of structural malformations. Consumption of 1 g/(kg · d) of formulated lycopene during gestation resulted in no signs of maternal toxicity or teratogenic effects in rats

## **STOT-Single Exposure:**

No data available

## Information on Lycopene

When rats were fed up to 20 mg/(kg · d) of lycopene as either formulated lycopene or tomato concentrate, the highest concentrations were found in the liver. When these rats were later placed on a lycopene-free diet, lycopene concentrations substantially declined, suggesting that the hepatic accumulation of lycopene is reversible.

## **STOT-repeated Exposure:**

No data available

## **Aspiration Hazard:**

No data available

## **Other information:**

## Information on Lycopene:

Based on the various safety studies reviewed, no adverse effects were observed at the highest intake level provided, that is, 3 g/(kg · d) of dietary or formulated lycopene. Therefore, a no-observed-adverse-effect level (NOAEL) of 3 g/(kg · d) is assumed. For a 70-kg man, the assumed NOAEL would be equivalent to 210 g/d. The median and 99th percentile of dietary lycopene intake have been estimated to be as high as 5.2 and 123 mg/d, respectively (11), which are substantially lower than the assumed NOAEL.

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

### **Inhalation:**

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

### **Skin contact:**

No adverse effects due to skin contact are expected.

### **Eye contact:**

Spill in the eyes will cause irritation.

**Ingestion:** Expected to be a low ingestion hazard.



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## 11.3 Symptoms related to the physical, chemical and toxicological characteristics

Lycopene may cause chest pain, diarrhoea, fat build-up under the skin, feeling of pressure in the stomach, gassiness, heart attack, indigestion, loss of appetite, nausea, rash, skin discoloration, stomach pain, stomach ulcer irritation, vomiting, and worsened hot flashes

## 11.4 Delayed and immediate effects and also 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 other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component

## 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.

## SECTION 14: Transport information

	Regulation Transport	Land transport ( US DOT )	Sea transport ( IMDG )	Air transport ( IATA/ICAO )
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 hazard class(es)			
	Hazard label(s)			
14.4	Packing group			
14.5	Environmental hazards			



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**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/Lycopene 10% LF /02

Version : 000

Effective Date : 05.05.2020

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

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



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## 16.3 Key literature references and sources for data

<https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/20850>

<https://static.usp.org/pdf/EN/referenceStandards/msds/1370860.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**