Safety Data Sheet

Divi's safety data sheet according to OSHA HCS

Product Name: Lycopene 5% DC/AF

Version: 000 Revision date: 08.05.2020

SECTION 1: Identification.

1.1 GHS Product identifier

Product name : Lycopene 5% DC/AF

1.2 Recommended use of the chemical and restrictions on use

Used for colorization and fortification of food and 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:

Not applicable

Disposal:

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

Pictograms

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

3.2 Mixtures: Modified starch, corn starch, Lycopene, Refined corn oil, DL-alpha-tocopherol, Sodium ascorbate.

Substance Name	CAS No	Ec No	Content ratio W/W %	Classification according Regulation (29 CFR 1910 (OSHA HCS)
Modified starch	66829-29-6	...	65.0 - 75.0%	Not classified as hazardous substance
Corn starch	9005-25-8	232-679-6	15.0 – 25.0%	Not classified as hazardous substance
Lycopene	502-65-8	207-949-1	5.0– 7.0%	Not classified as hazardous substance
Refined corn oil	8001-30-7	232-281-2	≤ 5.0%	Not classified as hazardous substance
Dl-alpha tocopherol	10191-41-0	233-466-0	≤ 5.0%	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

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:

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

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, 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.

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 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:

Avoid breathing dust. 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 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/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.

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

Avoid dust formation.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
Modified starch	66829-29-6	No data available
Corn starch	9005-25-8	OSHA PEL PEL: 15 mg/m3 (Total dust) ; PEL 5 mg/m3 (Respirable fraction) ; TWA : 15 mg/m3 (Total dust) ; TWA value 5 mg/m3 (Respirable fraction) ; ACGIH TLV TWA : 10 mg/m3
Lycopene	502-65-8	No data available
Refined corn oil	8001-30-7	ACGIH TLV-TWA:10 mg/m3 as oil NIOSH RELs-TWA:10 ppm (total dust), 5 ppm (respirable fraction) OSHA PEL-TWA:15 mg/m3 as oil
Dl-alpha tocopherol	10191-41-0	TWA 10 mg/m3 (Canada) OEL PEL 5 mg/m3 (US)

8.2 Appropriate engineering controls:

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.

Dust generating substances

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.

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. 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.

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	solid free flowing
Colour	Reddish
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
Flash point	No data available
Auto-ignition temperature	Not determined
Decomposition temperature	Not determined
P^H	3.5 – 4.5 (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	0.45 -0.6 g/cm3
Relative Vapour density	No data available
Particle Characteristics	No data available
Oxidising properties	Oxidizes when exposed to air 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

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

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:

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

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.

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			

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 5% DC/AF/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

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://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:

Notice to Reader

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: 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