



Safety Data Sheet

Divi's safety data sheet according to OSHA HCS

Product Name: Lutein 10% DC/AF

Version: 000

Revision date: 01.05.2020

SECTION 1: Identification

1.1 GHS Product identifier

Product name : Lutein 10% DC/AF

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)

H 317 May cause an allergic skin reaction

Precautionary statement(s)

Prevention:

P261: Avoid breathing dust/vapour

P272: Contaminated work clothing should not be allowed out of the workplace.

P280: Wear protective gloves.

Response:

P302 + P352: IF ON SKIN: Wash with plenty of water

P333 + P313: If skin irritation or rash occurs: Get medical advice/attention.

P321: Specific treatment

P362 + P364: Take off contaminated clothing and wash it before reuse.

Storage:

No data available

Disposal:

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P501: Dispose of contents/container according to local\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:** Material does not meet the criteria of a substance

3.2 **Mixtures:** : Modified starch, corn-starch, dried glucose syrup, Lutein, DI-alpha tocopherol, Sodium ascorbate

Substance Name	CAS No	Ec No	Content ratio W/W %	Classification according Regulation (29 CFR 1910 (OSHA HCS)
Modified Corn starch	66829-29-6	----	35.0 - 45.0%	Not classified as hazardous substance
Corn Starch	9005-25-8	232-679-6	20.0 - 30.0%	Not classified as hazardous substance
Dried glucose syrup	68131-37-3	268-616-4	20.0 - 30.0%	Not classified as hazardous substance
Lutein	127-40-2	204-840-0	10.0 – 12.0%	Not classified as a hazardous substance
DI alpha Tocopherol	10191-41-0	233-466-0	≤ 5.0%	Skin sensitization.Category 1B
Sodium ascorbate	134-03-2	205-126-1	≤ 2.0%	Not classified as a hazardous substance

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 thoroughly 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.



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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:

May cause allergic skin reaction

4.3 Indication of immediate medical attention and special treatment needed

Treatment: Symptomatic treatment (decontamination, vital functions), no known specific antidote.

SECTION 5: Fire fighting measures

5.1 Extinguishing media:

Suitable extinguishing media: Water spray, foam, carbon dioxide, dry powder

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, harmful vapours.

5.3 Advice for fire-fighters:

Wear self-contained breathing apparatus for firefighting if necessary.

Wear standard protective equipment and self-contained breathing apparatus for firefighting if necessary.

Wear self-contained respiratory protective device. Use water spray to cool unopened containers.

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, self-contained breathing apparatus should be used to avoid



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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 chemical-protective clothing.

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

Wear safety glasses with side-shields.

Wear chemical resistant protective gloves.

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 amounts: Sweep/shovel up.

For large amounts: Rinse away with water.

Pick up spilled material and containerize for recovery or disposal.

Correctly dispose of recovered product immediately.

Pick up spilled material and containerize for recovery or disposal. Vacuum area or flush with water to remove residues

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:

No data available

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



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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 breathe dust. No 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. Do not store in direct sunlight. Handle in accordance with good industrial hygiene and safety practice. 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 room temperature & dry conditions in 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.

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/m ³ (Total dust) ; PEL 5 mg/m ³ (Respirable fraction) ; TWA : 15 mg/m ³ (Total dust) ; TWA value 5 mg/m ³ (Respirable fraction) ; ACGIH TLV TWA : 10 mg/m ³
Dried Glucose Syrup	68131-37-3	TWA: 15 (mg/m ³) from OSHA (PEL) Inhalation Total TWA: 5 (mg/m ³) from OSHA (PEL) Inhalation Respirable
Lutein	127-40-2	No data available
DI alpha Tocopherol	10191-41-0	OSHA- PEL:10 mg/m ³ (Total dust) TWA: 5 mg/m ³ (Respirable dust)
Sodium ascorbate	134-03-2	No data available

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



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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.



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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/dust 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 powder
Odour	None
Meltingpoint/freezingpoint	Not applicable
Initial boiling point/boiling range	Not applicable
Flammability	No data available
Upper/lower flammability or explosive limits	No data available
Flash point	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
pH	4.5 -6.5 (10% Dispersion in water)
Kinematic viscosity	No data available
Solubility(ies)	Dispersible in water
Partition- coefficient: n-Octanol/water	No data available
Vapour pressure	No data available
Density and/or relative density	0.45 - 0.6 g/cm ³
Relative Vapour density	No data available
Particle Characteristics	No data available
Oxidising properties	Oxidise when exposed to air

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

No data available



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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

May Dust explosion hazard.

10.4 Conditions to avoid

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.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity: Classification criteria are not met

ATE Oral Rat >5000mg/Kg

Information on Lutein

Oral : LD50 Rat > 2000 mg/kg

A 4-week pilot toxicity study was conducted in Han Wistar rats to determine the oral toxicity following administration in the diet of a lutein product derived from marigold flowers. Seven dose groups were used (0, 2.6, 7.7, 26.0, 77.3, 260 and 773.2 mg of lutein product/kg bw/day). The study was performed essentially according to OECD Test Guideline 407. The authors concluded that oral administration of this lutein product to rats at dose levels up to 773.2 mg/kg bw/day (highest dose level tested, corresponding to 611 mg lutein/kg bw/day since the lutein content of the product was 79%) for 4 weeks did not result in test article related toxicity and was well tolerated by the rats

The single-dose administration of lutein and lutein ester up to a concentration of 4 g/kg did not produce any mortality. The body weight of the animals did not differ much during the period of study. The food consumption was found to be low initially, probably due to the high quantity of sunflower oil administered. On the third day onwards, the food consumption was found to be similar to that of the controls. Diarrhea was observed in all the animals for the first 2 days, and the reason can be attributed to the administration of sunflower oil and from third day onwards diarrhea was decreased. The results indicated that lutein and lutein ester did not produce any mortality even up to a concentration of 4 g/kg.

Skin corrosion/ irritation

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



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Eye damage/irritation

Not irritating to the eyes. 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 Guinea 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 Lutein

EFSA (2006) describes a study in which the mutagenic potential of a lutein product (from marigold petals, containing 79% lutein and 5% zeaxanthin) was investigated in the Ames test according to OECD Test Guideline 471. Salmonella typhimurium strains TA1535, TA97, TA98, TA100, and TA102 with and without metabolic activation (S9 fraction from rat liver), were used. Two formulations were tested: beadlets containing 10% lutein product (158-15 800 µg beadlets/plate (i.e. 12.8-1280 µg lutein/plate)) and the lutein product as such (15.8 – 1580 µg lutein product/plate (i.e. 12.8-1280 µg lutein/plate))

No toxicity was apparent for any strain, except TA102, which showed reduced growth, most prominently in the absence of S9. No increase in the number of mutant colonies was observed with the lutein product.

Carcinogenicity

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

Information on Lutein

No chronic toxicity/carcinogenicity studies have been described for lutein



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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 Lutein

No multigeneration studies are available. JECFA (2006) describes one developmental toxicity study.

Female Sprague-Dawley rats (mated when they were aged 10–13 weeks) were given diets mixed with beadlets containing 10% lutein (from marigold extract; 79% lutein, 5% zeaxanthin), corresponding to dietary intakes of 0, 252, 535 and 1118 mg/kg bw/day, from day 6 to day 20 of gestation. Placebo beadlets were used to ensure similarity in the total concentration of beadlets received by all treatment groups. The study complied with GLP guidelines.

There was a slight, dose related increase in the incidence of rudimentary extra lumbar ribs in the groups receiving the intermediate and highest doses. However, these findings were not considered to be of toxicological significance owing to the known reversibility of this minor skeletal finding. Analyses of blood samples showed dose-dependent increases in mean total plasma concentrations of lutein on days 7 and 16 of gestation. Mean total plasma lutein concentrations were approximately 80% higher on day 16 of gestation than on day 7. These data indicate that animals were adequately exposed to lutein throughout the experimental period. The NOAEL in this study of embryotoxicity/teratogenicity in rats was 1000 mg/kg bw/day, the highest dose tested

STOT-Single Exposure

No data available

STOT-repeated Exposure

No data available

Aspiration Hazard

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

Overdose symptoms may include increased thirst or urination, severe stomach pain, vomiting, bloody diarrhoea, black and tarry stools, hair loss, peeling skin, tingly feeling in or around your mouth, changes in



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menstrual periods, weight loss, severe headache, severe back pain, blood in your urine, pale skin, easy bruising or bleeding, severe drowsiness, slow heart rate, shallow breathing, weak and rapid pulse, confusion, muscle weakness, cold and clammy skin, blue lips, and seizure (convulsions).

11.4 Delayed and immediate effects and chronic effects from short term and long term exposure:

No data available

11.5 Other information:

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

SECTION 14: Transport information

	Regulation Transport	Land transport (US DOT)	Sea transport (IMDG)	Air transport (IATA/ICAO)
14.1	UN No.	Not regulated as a dangerous goods	Not regulated as a dangerous goods	Not regulated as a 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/Lutein 10% DC/AF/02

Version : 000

Effective Date : 01.05.2020

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

ICAO: International Civil Aviation Organization.

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

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://static.usp.org/pdf/EN/referenceStandards/msds/1370804.pdf>

<https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/79663>

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

16.4 Further information:

Training advice :

Consult your safety supervisor 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