



Safety Data Sheet

Divi's safety data sheet according to OSHA HCS

Product Name: Lutein 20% SAF

Version: 000

Revision date: 01.05.2020

SECTION 1: Identification

1.1 GHS Product identifier

Product name : Lutein 20% SAF

1.2 Recommended use of the chemical and restrictions on use

Used as Nutrient in food and dietary supplement applications.

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

E-mail: mail@divislaboratories.com

Website: www.divislabs.com

1.4 Emergency phone number: +91-8922-248944

SECTION: 2 Hazards Identification

2.1 Classification of the substance or mixture:

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

Skin sensitisation category 1B.

2.2 GHS label elements, including precautionary statements

2.2.1 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:

No data available

Disposal:

Dispose of contents/container in according 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: Material does not meet the criteria of a substance

3.2 Mixtures : Safflower oil, Lutein, DL-alpha Tocopherol

Substance Name	CAS No	Ec No	Content ratio W/W %	Classification according Regulation (29 CFR 1910 (OSHA HCS)
Safflower oil	8001-23-8	232-276-5	70.0 – 80.0%	Not classified as hazardous substance
Lutein	127-40-2	204-840-0	20.0 – 23.0%	Not classified as hazardous substance
DL-alpha Tocopherol	10191-41-0	233-466-0	≤ 2.0%	Skin sensitisation 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 develops seek medical attention.

On inhalation:

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

On skin contact:

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

Get medical attention if irritation develops

On eye contact:

Check for and remove any contact lenses. In case of Contact, immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower lids. Get medical attention if irritation occurs.

On ingestion:

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

4.2 Most important symptoms/effects, acute and delayed

Symptoms/effects

May cause allergic skin reaction

4.3 Indication of immediate medical attention and special treatment needed

Treatment: Symptomatic treatment (decontamination, vital functions).



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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:

Harmful vapours 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.

Personal protective equipment

Wear safety glasses with side-shields.

Wear chemical resistant protective gloves.

Wear protective clothing.

Eye wash fountains and safety showers must be easily accessible.

6.2 Environmental precautions

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



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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. 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 and 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

Provide suitable exhaust ventilation at the processing machines. Ensure thorough ventilation of stores and work areas. Avoid contact with the skin, eyes and clothing

Fire preventions:

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.

Aerosol and dust generation preventions:

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.

Environmental precautions:

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.

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



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7.2 Conditions for safe storage, including any incompatibilities

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

7.3 Specific end use(s)

Recommendations: No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

8.1.1 Occupational exposure limit(s)

Substance name	CAS No	Occupational exposure limits
Safflower oil	8001-23-8	No data available
Lutein	127-40-2	No data available
DL-alpha Tocopherol	10191-41-0	TWA 10 mg/m ³ (Canada) OEL PEL 5 mg/m ³ (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 eye wash 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	Orange red colour
Odour	None to faint
Meltingpoint/freezingpoint	-10°C to -17°C (For freezing point)
Initial boiling point/boiling range	>350°C (For safflower oil)
Flammability	No data available
Upper/lower flammability or explosive limits	No data available
Flash point	>288°C (For safflower oil)
Auto-ignition temperature	No data available
Decomposition temperature	No data available
pH	No data available
Viscosity Dynamic	≤ 5000.0 Cp at ambient temperature
Solubility(ies)	Not soluble in water Sparingly soluble in vegetable oils and fats. Soluble in lipophilic solvents
Partition- coefficient: n-Octanol/water	No data available
Vapour pressure	No data available
Density and/or relative density	0.90 - 0.95 g/cm ³ (20°C)
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 all sources of ignition exposure to heat, light & Moist air



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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 dioxides and carbon monoxide.

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.

Serious 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:



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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

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

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.



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

Skin contact:

No adverse effects due to skin contact are expected.

Eye contact:

No adverse effects due to eye contact are expected.

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 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 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



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12.3 Bio accumulative potential:

No data available

12.4 Mobility in soil:

No data available

12.5 Results of PBT and VPvB assessment

No data available

12.6 Other adverse effects:

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods.

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

SECTION 14: Transport information

	Regulation Transport	Land transport (US DOT)	Sea transport (IMDG)	Air transport (IATA/ICAO)
14.1	UN No.	Not classified as dangerous goods	Not classified as dangerous goods	Not classified 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 MARPOL73/78 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



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SECTION 16: Other information

16.1 Information on revision

Product code : II/Lutein 20% SAF/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

DOT: Department of Transportation

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System

ACGIH: American conference of governmental industrial hygienist

OSHA: Occupational safety & health administration

TLV: Threshold limit value

TWA: Time weighted average

PEL: Permissible exposure limit

STOT: Specific target organ toxicity

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

TSCA: Toxic Substance control act

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

16.3 Key literature references and sources for data

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

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

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

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.

16.4 Further information:

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