Safety Data Sheet

Divi's safety data sheet according to OSHA HCS

Product Name: Beta-Carotene 22% LF
Version: 000 Revision date: 10.04.2020

SECTION 1: Identification.

1.1 GHS Product identifier

Product name : Beta-Carotene 22% LF

1.2 Other means of identification

None

1.3 Recommended use of the chemical and restrictions on use

Used as Nutrient in food and dietary supplement applications.

1.4 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

1.5 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)

Sensitization – Skin (Category 1B)

Eye Damage/Irritation (Category 2)

2.2 GHS label elements,including precautionary statements

Signal word(s)

Warning

Hazard statement(s)

May cause an allergic skin reaction

Causes serious eye irritation

Precautionary statement(s)

Prevention:

Avoid breathing mist/vapours/spray.

Wash hands thoroughly after handling

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

Wear protective gloves/eye protection/ face protection.

Response:

IF ON SKIN: Wash with plenty of water.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

If eye irritation persists: Get medical advice/attention.

Specific treatment

Take off contaminated clothing and wash it before reuse

Storage:

No data available

Disposal:

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

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, Beta carotene, Citric acid, Dl alpha tocopherol, Ascorbyl palmitate.

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	65.0 – 75.0%	Not classified as a hazardous substance
Beta carotene	7235-40-7	230-636-6	22.0 – 24.0%	Eye Damage/Irritation (Category 2) Self-heating in large quantities; may catch fire category 2
Citric acid	77-92-9	201-069-1	≤ 5.0%	Not classified as a hazardous substance
Dl alpha tocopherol	10191-41-0	233-466-0	≤ 5.0%	Skin sensitization ,Category -1B
Ascorbyl palmitate	137-66-6	205-305-4	≤ 5.0%	Eye Damage/Irritation (Category 2)

SECTION 4: First aid measures

4.1 Description of necessary first-aid measures

4.1.1 General information:

On inhalation:

Move to fresh air and keep patient at rest. Seek medical attention immediately

On skin contact:

Remove contaminated clothing. Flush area with large amounts of water.Use soap.Seek medical attention.

On eye contact:

Flush with water while holding eyelids open for atleast 15 minutes. Seek medical attention immediately

On ingestion:

Never give anything by mouth to an unconscious person. Wash out mouth with water. Seek medical attention immediately.

4.2 Most important symptoms/effects, acute and delayed

Symptoms/effects:

May cause irritation to skin, eye and respiratory tract.

Causes skin sensitization.

4.3 Indication of immediate medical attention and special treatment needed

Treatment: Provide general supportive measures and treat symptomatically.

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:

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 emergencyresponders:

Avoid contact with the skin, eyes and clothing.

Use with local exhaust ventilation.

Wear self-contained, breathing apparatus and protective Clothing to prevent contact with skin and eyes.

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

Wear safety glasses with side-shields.

Wear chemical resistant protective gloves.

Wear protective clothing.

Eye wash fountains and safety showers must be easily accessible.

6.2 Environmental precautions:

Do not empty into drains. Do not discharge into drains/surface waters/groundwater

6.3 Methods and material for containment and cleaning up

6.3.1 For containment:

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:

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:

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

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.

Keep away from food, drink and animal feeding stuffs.

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

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

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

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	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
Beta carotene	7235-40-7	No data available
Citric acid	77-92-9	ACGIH: 10 mg/m3 TWA (Total Inhalable fraction); 3 mg/m3 TWA (Respirable fraction) OSHA: 15 mg/m3 TWA (Total dust); 5 mg/m3 TWA (Respirable Fraction)
Dl alpha tocopherol	10191-41-0	TWA 10 mg/m3 (Canada) OEL PEL 5 mg/m3 (US)
Ascorbyl palmitate	137-66-6	Dusts not otherwise classified: 8hr TWA = 10 mg/m3

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:

Avoid contact with eyes. Wear approved safety glasses with side shields or cover goggles if eye Contact is possible

Skin protection:

Impervious disposable protective clothing is recommended if skin contact with drug product is Possible and for bulk processing operations

Hand protection:

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (Without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Body protection:

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

Respiratory protection:

If ventilation is not sufficient to effectively prevent buildup of dust, appropriate NIOSH respiratory protection must be provided.

Thermal hazards:

Wear appropriate thermal protective clothing, when necessary.

SECTION 9: Physical and chemical properties and safety characteristics

9.1 Basic physical and chemical properties

Property	Remarks / Guidance
Physical state	Liquid - Suspension
Colour	Reddish
Odour	None to faint
Meltingpoint/freezingpoint	-10°C to -18°C
Initial boiling point/boiling range	402.8° C (For corn oil)
Flammability	No data available
Upper/lower flammability or explosive limits	No data available
Flash point	254°C (For corn oil)
Auto-ignition temperature	Not determined
Decomposition temperature	Not determined
P^{H}	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/cm3 (25°C)
Relative Vapour density	No data available
Particle Characteristics	No data available
Viscosity Dynamic	≤1000.0 cp at ambient temperature
Oxidising properties	Based on its structural properties the product is not classified

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:

Stable 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

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 Beta Carotene

Acute toxicity oral:

The acute oral toxicity of the test item was investigated under GLP in Han Wistar rats of both sexes (10 animals) according to OECD TG 401. Single oral dose administration of 2000 mg-kg body weight of the test item was well tolerated. No mortalities occurred and no clinical signs indicative of reduced health or behavioural changes

were observed in the animals. No macroscopic findings were noted at scheduled necropsy. According to OECD and EU guidelines, the test substance is considered to present no significant acute toxic risk if swallowed

Skin corrosion/ Irritation:

Mixture is not irritating to skin.

Information on Beta-carotene:

The primary skin irritation potential of the test item was investigated under GLP according to OECD TG 404. The application of the test item to the skin resulted in very slight erythema in all animals 1 hour after removal of the dressing, persisting in one female animal until the 24 -hour reading. Red staining of the treated skin area produced by the test item was noted in all animals from the 1-hour reading to the 7-day reading and persisted in one female animal until the 10-day reading. No corrosive effects were noted on the treated skin of any animal at any of the measuring intervals and no clinical signs were observed. Thus, the test item did not induce significant or irreversible damage to the skin.

Serious eye damage/irritation:

Mixture may cause irritation to eye.

Information on Beta-carotene

Considering that in the BCOP study a negative result was reported in the valid study and in the EpiOcular study the first test gave a borderline positive result, and the positive result in the second test may have been due to the difficulty in removing the test item from the cornea, a precautionary classification of Eye Irritation Category 2 was concluded.

Information on citric acid

Study, apparently conducted according to OECD 405 and GLP, reported that a 30% aqueous solution of the test substance caused well defined to moderate conjunctival irritation that had not fully resolved after 14 days. A 10% solution was associated with weak to moderate conjunctival effects, resolved after 7 days. Given the 30% solution effects would have been allowed to dissipate for 21 days, it is likely the test substance would not be considered irritating to the eyes according to EU criteria.

Information on Ascorbyl palmitate:

The possible eye hazard potential of Ascorbyl palmitate was tested through topical application on two tissues for 6 hours. The positive control had a mean cell viability of 41% after 6 hours ± 15 minutes exposure. The absolute mean OD570 (optical density at 570 nm) of the negative control tissues was within 0.8 and 2.5. The standard deviation value of the percentage viability of two tissues treated identically was less than 10%. Eye hazard potential is expressed as the remaining cell viability after exposure to the test item. The relative mean tissue viability obtained after 6 hours ± 15 minutes treatment with Ascorbyl palmitate compared to the negative control tissues was 33%. Since the mean relative tissue viability for Ascorbyl palmitate was below 60% after 6 hours ± 15 minutes treatment it is considered to be potentially irritant or corrosive to the eye.

Respiratory or skin sensitisation:

Mixture may cause skin sensitization.

Information on Beta Carotene

In a GLP and the OECD guideline 429 conform study, the test item beta-Carotene 10 % CWS Star suspended in ethanol: deionised water (3:7) was assessed for its possible contact allergenic potential. For this purpose, a local lymph node assay was performed using test item concentrations of 5, 10 and 25 % (w/w). The animals did not show any clinical signs during the course of the study and no cases of mortality were observed

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

Germ cell mutagenicity:

Mixture is neither toxic nor genotoxic.

Information on Beta-carotene

Neither toxic nor genotoxic activity of the test compound was apparent under these test conditions. Thus, it can be concluded that beta-Carotene is not mutagenic in the Ames test with and without metabolic activation.

Carcinogenicity:

Assessment of carcinogenicity No data available

Reproductive Toxicity:

Assessment of reproduction toxicity No data available

STOT-Single Exposure:

No data available

STOT-repeated Exposure:

No data available

Aspiration Hazard:

No data available

Other information:

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:

Mist 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

May cause Nausea, dizziness, vomiting, disorientation, and blurring vision after taking large doses of beta carotene.

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:

Mixture is not considered to have aquatic toxicity.

Information on Beta-carotene

A study (presumably under static conditions) on the acute toxicity of beta-Carotene to rainbow trouts (Salmo gairdneri L., now Oncorhynchus mykiss) was conducted over a period 48 hours. Fingerlings of 4 to 8 cm body length were exposed to different concentrations of the test substance. The test temperature was 14 ± 1 °C. The substance was defined as barely toxic on the basis of the test results, i.e. no toxic effects were observed up to a (presumably nominal) test concentration of 1000 mg/L.

The test results showed that the test item had no effects on daphnids up to nominal concentrations of 100 mg/L. The EC50 (after 48 hr) was determined to be >100 mg/L based on the nominal concentration. Due to the low water solubility of beta-Carotene, precipitation of the test substance was observed throughout the study. The actually dissolved concentrations were considerable below nominal concentrations. The EC50 was > 3.23 mg/L based on the measured concentrations at study initiation and finalisation

12.2 Persistence and degradability:

Mixture is not readily biodegradable.

Information on Beta-carotene

The test item attained 30% biodegradation after 28 days and therefore cannot be considered to be readily biodegradable under the strict terms and conditions of OECD Guideline No. 301B.

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			

14.6 Special precautions for user:

None

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:

No data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

US regulations:

TSCA section 12(b) Export notification (40 CFR 707, subpt. D): Not Regulated

CERCLA Hazardous substances list (40 CFR 302.4): Not listed

SARA 304 Emergency release notification.: Not Regulated.

SECTION 16: Other information

16.1 Preparation information

Product code : II/Beta carotene 22% LF/02

Version : 000

Effective Date : 10.04.2020

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/fr/information-on-chemicals/cl-inventory-database/-/discli/details/119366

https://static.usp.org/pdf/EN/referenceStandards/msds/1065480.pdf

https://echa.europa.eu/it/information-on-chemicals/cl-inventory-database/-/discli/notification-details/224486/901107

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

https://echa.europa.eu/da/registration-dossier/-/registered-dossier/25238/7/4/1

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