Safety Data Sheet

Divi's safety data sheet according to OSHA HCS

Product Name: Beta carotene 1% SD
Version: 000 Revision date: 15.04.2020

SECTION 1: Identification

1.1 GHS Product identifier

Product name : Beta-carotene 1% SD

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

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

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: Gum Acacia, Maltodextrin, Sucrose, Coconut oil, Sodium Ascorbate, Silicon Dioxide, DL-alpha Tocopherol, Beta-carotene.

Substance Name	CAS No	Ec No	Content ratio W/W %	Classification according Regulation (29 CFR 1910 (OSHA HCS)
Gum Acacia	9000-01-5	232-519-5	30.0 - 35.0%	Not classified as hazardous substance
Maltodextrin	9050-36-6	232-940-4	30.0 - 35.0%	Not classified as hazardous substance
Sucrose	57-50-1	200-334-9	10.0 - 20.0%	Not classified as hazardous substance
Coconut oil	8001-31-8	232-282-8	10.0 - 20.0%	Not classified as hazardous substance
Sodium Ascorbate	134-03-2	205-126-1	≤ 5.0%	Not classified as hazardous substance
Silicon Dioxide	7631-86-9	231-545-4	≤ 2.0%	Not classified as hazardous substance
DL-alpha Tocopherol	10191-41-0	233-466-0	≤ 2.0%	Skin Sensitization. Category 1B
Beta carotene	7235-40-7	230-636-6	1.0 – 1.3%	Self-heating substances and mixtures (Category 2) Eye damage/irritation (Category 2)

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 skin with soap and water as a precaution

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:

If swallowed, do not induce vomiting. Rinse mouth with water. Never give anything by mouth to an unconscious person. Get immediate medical attention.

4.2 Most important symptoms/effects, acute and delayed

Symptoms/effects:

May cause irritation to skin, eyes and respiratory tract

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, carbon dioxide, dry chemical powder or Chemical foam.

Unsuitable extinguishing media:

Water jet.

5.2 Special hazards arising from the substance or mixture:

Gum acacia

As with all carbohydrate materials, a dust explosion hazard exists if the dust concentration in air is high. Spray-dried gum acacia is a St class 1 powder, with Kst = 63 bar m/s.

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 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. 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.

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:

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 absorbed material in accordance with regulations.

6.3.2 For cleaning up:

Cleaning operations should carried out only while wearing breathing apparatus.

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:

Avoid breathing dust, vapour, mist or gas. 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

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

Environmental precautions:

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. Store work clothing separately

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.

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:

Avoid dust formation. 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 Limit(s)
Gum Acacia	9000-01-5	TWA 10mg/m3
Maltodextrin	9050-36-6	TWA: 10 (mg/m3) from ACGIH (TLV)US TWA: 15 (mg/m3) from OSHA (PEL) US
Sucrose	57-50-1	OSHA PEL: 15 mg/m3 total dust; 5 mg/m3 respirable dust ACGIH TLV: 10 mg/m3 total dust

Coconut oil	8001-31-8	Coconut oil,10 mg/m3 NIOSH TWA
Sodium Ascorbate	134-03-2	No data available
Silicon Dioxide	7631-86-9	No data available
DL-alpha Tocopherol	10191-41-0	TWA 10 mg/m3 (Canada) OEL PEL 5 mg/m3 (US)
Beta carotene	7235-40-7	No data available

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

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 if there is potential for airborne dust exposures. 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, Suitable materials, plastic and rubber

Body protection:

Body protection must be chosen depending on activity and possible exposure, e.g. head protection, apron, protective Shoes, chemical-protection suit.

Respiratory protection:

Wear respiratory protection if ventilation is inadequate. Wear a NIOSH-certified (or equivalent) organic vapour/particulate respirator. Suitable respiratory protection for higher concentrations or long-term effect. Breathing protection if breathable aerosols/dust are formed.

Thermal hazards: None

SECTION 9. Physical and chemical properties and safety characteristics

9.1 Basic physical and chemical properties

Property	Remarks / Guidance
Physical state	Solid- free flowing fine powder
Colour	Orange powder
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}	5.0 - 6.0 (when 1.0gm dispersed in 100ml 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	0.7 – 0.85 g/cm3
Relative Vapour density	No data available
Particle Characteristics	No data available
Oxidising properties	Oxidizes in presence of oxygen when kept in open conditions

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

Corrosion to metals: Corrosive effects to metal are not anticipated.

SECTION 10: Stability and Reactivity

10.1 Reactivity:

No hazardous reactions if stored and handled as prescribed /indicated.

10.2 Chemical stability:

No hazardous reactions when stored and handled according to instructions.

10.3 Possibility of hazardous reactions:

No hazardous reactions when stored and handled according to instructions .

10.4 Conditions to avoid:

Avoid dust formation and electro-static charge .Avoid all sources of ignition exposure to heat, light & Moist air.

10.5 Incompatible materials:

Atmospheric oxygen, Strong oxidizing agents, reducing agents, strong acids, strong bases.

10.6 Hazardous decomposition products:

No hazardous decomposition products if stored and handled as prescribed /indicated.

Decomposition in abnormal conditions forms Carbon oxides.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity: Classification criteria are not met

ATE mix Oral Rat > 5000mg/kg

Information on 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 is not irritating to eyes.

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

Respiratory or skin sensitisation:

Mixture may cause skin sensitization

Product is not tested

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: D,L-alpha-Tocopherol

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:

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:

Not evaluated

Reproductive Toxicity:

Not evaluated

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

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 1% SD/02
Version	: 000
Effective Date	: 15.04.2020
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://static.usp.org/pdf/EN/referenceStandards/msds/1065480.pdf

https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/119366

https://echa.europa.eu/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