

1. Identification

Product identifier Beta Carotene System Suitability

Other means of identification

Catalog number 1065491

Chemical name Dunaliella mixed carotinoids

Recommended use Specified quality tests and assay use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Company name U. S. Pharmacopeia

Address 12601 Twinbrook Parkway
Rockville
MD
20852-1790
US

Telephone RS Technical Services 301-816-8129

Website www.usp.org

E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300
Canada
CHEMTREC outside US & +1 703-527-3887
Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Not classified.

OSHA hazard(s) Not classified.

Label elements

Hazard symbol No symbol.

Signal word Not available.

Hazard statement Not available.

Precautionary statement

Prevention Not available.

Response Not available.

Storage Not available.

Disposal Not available.

Hazard(s) not otherwise classified (HNOC) Not classified.

3. Composition/information on ingredients

Mixture

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Ascorbic Acid		50-81-7	1

Non-hazardous components

Chemical name	Common name and synonyms	CAS number	%
Gum Arabic		9000-01-5	53
Lipid/Oil		No Data	17.5
Maltodextrin		9050-36-6	15
Beta Carotene		7235-40-7	5 - < 10
Water		7732-18-5	4.5
Tocopherol		1406-66-2	1

Non-hazardous components

Chemical name	Common name and synonyms	CAS number	%
Citric Acid		77-92-9	0.5
Related Impurities		No Data	< 1
Alpha Carotene		7488-99-5	< 0.3
Cryptoxanthin		472-70-8	< 0.1
Lutein		127-40-2	< 0.1
Zeaxanthin		144-68-3	< 0.1

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Not available.
Indication of immediate medical attention and special treatment needed	Treat symptomatically.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Exposure limit values

Industrial Use

Components	Type	Value
Ascorbic Acid (CAS 50-81-7)	TWA	10 mg/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

No exposure standards allocated.

Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection

Hand protection

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other

For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory protection

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Thermal hazards

Not available.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance

Brownish red powder.

Physical state

Solid.

Form

Powder.

Odor

Not available.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

Not available.

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

Not available.

Flammability limit - upper (%)

Not available.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor density

Not available.

Relative density

Not available.

Solubility in water

Not available.

Partition coefficient (n-octanol/water)

Not available.

Decomposition temperature

Not available.

Viscosity Not available.

Other information

Specific gravity > 0.5

10. Stability and reactivity

Reactivity No reactivity hazards known.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid None known.

Incompatible materials None known.

Hazardous decomposition products Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion Based on available data, the classification criteria are not met.

Inhalation Due to lack of data the classification is not possible.

Skin contact Due to lack of data the classification is not possible.

Eye contact Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical, and toxicological characteristics Not available.

Acute toxicity Based on available data, the classification criteria are not met.

Components	Species	Test Results
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Ascorbic Acid (CAS 50-81-7)

Oral

LD50

Mouse

3367 mg/kg

Rat

11900 mg/kg

Beta Carotene (CAS 7235-40-7)

Oral

LD50

Dog

> 8000 mg/kg

Rat

> 5000 mg/kg

Citric Acid (CAS 77-92-9)

Acute

Dermal

LD50

Rat

> 5000 mg/kg

Oral

LD50

Mouse

5040 mg/kg

Rat

6730 mg/kg

Lutein (CAS 127-40-2)

Oral

LD50

Rat

> 2000 mg/kg

Skin corrosion/irritation Due to lack of data the classification is not possible.

Serious eye damage/eye irritation Due to lack of data the classification is not possible.

Local effects

Citric Acid

Irritancy test
Result: Irritant.
Species: Rabbit
Organ: Eyes
Severity: Severe.
Irritancy test
Result: Irritant.
Species: Rabbit
Organ: Skin
Severity: Moderate.

Local effects

Ascorbic Acid

Irritancy test
Result: Non-irritant.
Species: Rabbit
Organ: Eyes

Beta Carotene

Irritancy test
Result: Non-irritant.
Species: Rabbit
Organ: Eyes

Lutein

Irritancy test
Result: Non-irritant.
Species: Rabbit
Organ: Eyes

Ascorbic Acid

Irritancy test
Result: Non-irritant.
Species: Rabbit
Organ: Skin

Beta Carotene

Irritancy test
Result: Non-irritant.
Species: Rabbit
Organ: Skin

Lutein

Irritancy test
Result: Non-irritant.
Species: Rabbit
Organ: Skin

Respiratory sensitization

Due to lack of data the classification is not possible.

Skin sensitization

Due to lack of data the classification is not possible.

Sensitization

Citric Acid

Local lymph node assay
Result: Non-sensitizing.
Species: Mouse
Organ: Skin

Germ cell mutagenicity

Due to lack of data the classification is not possible.

Mutagenicity

Beta Carotene

Ames test (with and without activation)
Result: Negative.

Citric Acid

Chromosome aberration assay in human lymphocytes
Result: Negative without activation. Positive with activation.
In vivo bone marrow micronucleus test in mice
Result: Negative.
Mouse lymphoma test
Result: Negative.
S. typhimurium and E. coli assays
Result: Negative.

Carcinogenicity

Due to lack of data the classification is not possible.

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Beta Carotene

1000 mg/kg/day Carcinogenicity study
Result: No evidence of carcinogenicity.
Species: Mouse
1000 mg/kg/day Carcinogenicity study
Result: No evidence of carcinogenicity.
Species: Rat
2.4 mg/kg/day Carcinogenicity study in ferrets
Result: Increased development of squamous cell metaplasia in lung tissue.
250 mg/kg/day Carcinogenicity study
Result: No evidence of carcinogenicity.
Species: Beagle dog
50000 ppm Carcinogenicity study
Result: No evidence of carcinogenicity.
Species: Mouse
Test Duration: 103 weeks
50000 ppm Carcinogenicity study
Result: No evidence of carcinogenicity.
Species: Rat
Test Duration: 103 weeks

Ascorbic Acid

Reproductive toxicity

Due to lack of data the classification is not possible.

Reproductivity

Ascorbic Acid

1000 mg/kg Reproductivity study

Result: No evidence of fetotoxicity or increased birth defects.

Species: Mouse

1000 mg/kg Reproductivity study

Result: No evidence of fetotoxicity or increased birth defects.

Species: Rat

Beta Carotene

1000 mg/kg/day Reproductivity study

Result: No adverse effects on reproductive function or embryo development and no increase in birth defects.

Species: Rat

Lutein

1000 mg/kg/day Reproductivity study

Result: No evidence of an increased incidence of embryotoxicity, fetotoxicity, or birth defects.

Species: Rat

Citric Acid

1000 mg/kg/day Reproductivity study

Result: No evidence of maternal toxicity, embryotoxicity, and fetotoxicity.

Species: Rat

Zeaxanthin

150 mg/kg/day NOAEL

Species: Rat

Beta Carotene

400 mg/kg/day Reproductivity study

Result: No embryotoxicity and no increase in birth defects.

Species: Rabbit

Specific target organ toxicity - single exposure

Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure

Due to lack of data the classification is not possible.

Aspiration hazard

Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity

No ecotoxicity data noted for the ingredient(s).

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

Not available.

Mobility in soil

Not available.

Other adverse effects

Not available.

13. Disposal considerations

Disposal instructions

This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose in accordance with all applicable regulations.

Local disposal regulations

Not available.

Hazardous waste code

Not available.

Waste from residues / unused products

Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

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

No information available.

15. Regulatory information

US federal regulations

CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

Issue date 12-30-2014

Version # 01

Further information Not available.

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