

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : BetaTab® 20% S Ph

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Ingredient for pharmaceutical products

1.3 Details of the supplier of the safety data sheet

Company : DSM Nutritional Products Europe Ltd
PO Box 2676
CH-4002 Basel

Telephone : +41618157777
Telefax : +41618157770
E-mail address of person responsible for the SDS : sds.nutritionalproducts@dsm.com

1.4 Emergency telephone number

+41 848 00 11 77 (Carechem 24 International)

SECTION 2: Hazards identification


2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

|| Eye irritation, Category 2 H319: Causes serious eye irritation.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

|| Hazard pictograms : 

Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.

Precautionary statements : **Prevention:**
P264 Wash skin thoroughly after handling.
P280 Wear eye protection/ face protection.
Response:
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Additional Labelling:

EUH208 Contains dl- α -tocopherol. May produce an allergic reaction.

2.3 Other hazards

Risk of dust explosion.

SECTION 3: Composition/information on ingredients

Brief description of the product : Mixture (preparation) containing active ingredient and auxiliary substances

3.1 Substances

Not applicable

3.2 Mixtures**Hazardous components**

Chemical name	CAS-No. EC-No. Registration number	Classification	Concentration (% w/w)
β,β -carotene	7235-40-7 230-636-6 01-2119967394-26	Eye Irrit. 2; H319	$\geq 20 - < 30$
3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol (dl- α -tocopherol)	10191-41-0 233-466-0 01-2120086658-39	Skin Sens. 1B; H317	$\geq 1 - < 5$

For explanation of abbreviations see section 16.

Further ingredients

Chemical name	CAS-No. EC-No. Registration number	GHS Classification	Concentration [%]
Starch	9005-25-8 232-679-6		$\geq 10 - \leq 30$

SECTION 4: First aid measures**4.1 Description of first aid measures**

- General advice : Move out of dangerous area.
Show this safety data sheet to the doctor in attendance.
- If inhaled : Move to fresh air.
Consult a physician after significant exposure.
- In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off with soap and plenty of water.
If symptoms persist, call a physician.
- In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.
- If swallowed : Clean mouth with water and drink afterwards plenty of water.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
Obtain medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No specific symptoms known.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water
Foam

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : None known.

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Consider dust explosion hazard.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment.
Ensure adequate ventilation.
Avoid dust formation.
Avoid breathing dust.

6.2 Environmental precautions

Try to prevent the material from entering drains or water courses.

6.3 Methods and material for containment and cleaning up

Pick up and arrange disposal without creating dust.

6.4 Reference to other sections

For personal protection see section 8.
For disposal considerations see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.

Advice on protection against fire and explosion : Avoid dust formation. Provide appropriate exhaust ventilation at places where dust is formed. Take precautionary measures against static discharges.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of work-day.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : To maintain product quality, do not store in heat or direct sunlight.

Keep container tightly closed and dry.

7.3 Specific end use(s)

Specific use(s) : Not applicable

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
starch	9005-25-8	TWA (inhalable dust)	10 mg/m ³	GB EH40
		TWA (Respirable dust)	4 mg/m ³	GB EH40
	The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m ⁻³ 8-hour TWA of inhalable dust or 4 mg.m ⁻³ 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limit.			
β,β-carotene	7235-40-7	TWA	1.5 mg/m ³	DSM Internal Limit

8.2 Exposure controls

Personal protective equipment

Eye protection : Safety glasses with side-shields

Hand protection : Consider the hazard characteristics of this product and any special workplace conditions when selecting the appropriate type of protective gloves.
Glove material: for example nitrile rubber

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : free flowing particles
Colour : reddish - brown
Odour : very faint
Odour Threshold : No information available.
pH : No data available
Melting point/range : not determined
Boiling point/boiling range : not determined
Flash point : Not applicable

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according to Regulation (EC) No. 1907/2006



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Flammability (solid, gas)	: May form combustible dust concentrations in air.
Vapour pressure	: Not applicable
Relative vapour density	: Not applicable
Density	: not determined
Water solubility	: dispersible
Partition coefficient: n-octanol/water	: Not applicable
Auto-ignition temperature	: No data available
Thermal decomposition	: Decomposes on heating. Potential for exothermic hazard
Explosive properties	: Not explosive
Oxidizing properties	: No data available

9.2 Other information

Combustibility index for deposited dust	: 3 (25 °C) : 3 (100 °C)
Dust explosion class	: St(H)1 (Milled sample, Median value of the tested sample 0.082 mm, Loss on drying 4.7 %; The value was determined in the modified Hartmann tube.)
Minimum ignition energy	: 10 - 30 mJ (Milled sample, Median value of the tested sample 0.082 mm, Loss on drying 4.7 %, EN 13821) The Minimum ignition energy (MIE) of a dust/air mix depends on the particle size the water content and the temperature of the dust. The finer and the dryer the dust the lower the MIE. : General remark: The indicated dust explosion characteristics are only valid for this product and are sensitive to the sample's parameters.
Powder volume resistivity	: ca. 3E+07 Ohmm (Product sample, Median value of the tested sample 0.31 mm, Loss on drying 4.2 %)
Minimum ignition temperature of a dust/air mix	: 330 °C (Median value of the tested sample 0.082 mm) determined in the BAM oven

SECTION 10: Stability and reactivity

10.1 Reactivity

No hazards to be specially mentioned.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Dust may form explosive mixture in air.

10.4 Conditions to avoid

Heat

10.5 Incompatible materials

Strong acids and strong bases
Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if used as directed.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

- Acute oral toxicity : Acute toxicity estimate : > 5,000 mg/kg
(Calculation method)
- Skin irritation : May cause skin irritation and/or dermatitis.
- Eye irritation
||β,β-carotene : Eye irritation (In vitro study, OECD Test Guideline 492)
- 3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol : slight irritation (Rabbit, Draize Test)
temporary redness
- Sensitisation : Does not cause skin sensitisation. (Mouse, Local Lymph Node Assay (LLNA), OECD Test Guideline 429)
Tested with a similar product containing 5% dl-alpha-tocopherol.
- Genotoxicity in vitro : not mutagenic, not genotoxic (Active ingredient)
- Carcinogenicity : No indication for carcinogenicity known.
- Teratogenicity : No indication for teratogenicity known.
- STOT - single exposure (Acute exposure) : The substance or mixture is not classified as specific target organ toxicant, single exposure.
- STOT - repeated exposure : NOAEL (feed admix, Dog) : 250 mg/kg bw/d
Test substance: Active ingredient
Chronic toxicity study (2 years)
- Further information : May cause skin discolorations.
: May cause irritation of respiratory tract.
- Aspiration toxicity : No aspiration toxicity classification

SECTION 12: Ecological information

12.1 Toxicity

No data is available on the product itself.

12.2 Persistence and degradability

Biodegradability
β,β-carotene : Inherently biodegradable.
88 - 99 % (17 d)
(OECD Test Guideline 302B)

No data is available on the product itself.

12.3 Bioaccumulative potential

Bioaccumulation : No data available

Partition coefficient: n-
octanol/water : Not applicable

12.4 Mobility in soil

Distribution among environ-
mental compartments : No data available

12.5 Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Additional ecological informa-
tion : There is no data available for this product.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Do not contaminate ponds, waterways or ditches with chemical or used container.
Do not dispose of waste into sewer.
Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging : Dispose of as unused product.
Do not re-use empty containers.

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Remarks : Not classified as dangerous in the meaning of transport regulations.

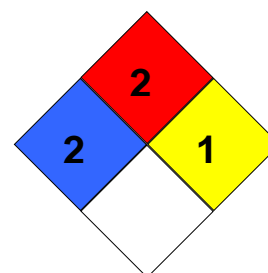
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

NFPA Classification : Health hazard: 2
Fire Hazard: 2
Reactivity Hazard: 1



15.2 Chemical safety assessment

Not applicable

SECTION 16: Other information

Full text of H-Statements

H317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.

Full text of other abbreviations

Eye Irrit. : Eye irritation
Skin Sens. : Skin sensitisation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical

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Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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