



CONSEIL DE L'EUROPE

# Betacarotene

# Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 03/04/2023 Revision date: 11/02/2025 Supersedes version of: 03/04/2023 Version: 2.0

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

1.1. Product identifier	
Product form Substance name Chemical name EC-No. CAS-No. Product code	<ul> <li>Substance</li> <li>Betacarotene</li> <li>Betacarotene</li> <li>230-636-6</li> <li>7235-40-7</li> <li>201700593</li> </ul>
1.2. Relevant identified uses of the substa	nce or mixture and uses advised against
Relevant identified uses	
Use of the substance/mixture	: Scientific research and development Technical testing and analysis For professional use only
Function or use category	: Laboratory chemicals
Uses advised against	
Restrictions on use	: Not for food, drug or home use
1.3. Details of the supplier of the safety da	ta sheet
European Directorate for the Quality of Medicines & EDQM, Council of Europe 7, Allée Kastner, CS30026 F 67081 Strasbourg France T +33(0)388412035, F +33(0)388412771 sds@edqm.eu, www.edqm.eu	& Healthcare
1.4. Emergency telephone number	
Emergency number	: +33(0)390215608
SECTION 2: Hazards identification	
2.1. Classification of the substance or mix	ture
Classification according to Regulation (EC) No.	1272/2008 [CLP]
Self-Heating Substances and Mixtures, Category 2 Serious eye damage/eye irritation, Category 2 Full text of H- and EUH-statements: see section 16	H319
Adverse physicochemical, human health and en	nvironmental effects
Causes serious eye irritation. Self-heating in large of	quantities; may catch fire.

2.2. Label elements

Hazard pictograms (CLP)	
	GHS02 GHS07
Signal word (CLP)	: Warning
Hazard statements (CLP)	: H252 - Self-heating in large quantities; may catch fire.
	H319 - Causes serious eye irritation.
Precautionary statements (CLP)	: P235 - Keep cool.
<u>-</u> ( )	P264 - Wash hands, forearms and face thoroughly after handling.

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	<ul> <li>P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.</li> <li>P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</li> <li>P337+P313 - If eye irritation persists: Get medical advice/attention.</li> <li>P407 - Maintain air gap between stacks or pallets.</li> <li>P413 - Store bulk masses greater than at temperatures not exceeding .</li> <li>P420 - Store separately.</li> </ul>
Labelling according to: Exemption for inner packaging	
No labelling required	
2.3. Other hazards	

Other information

: Active substance (in pharmaceutical products). Warning - substance not yet tested completely.

## SECTION 3: Composition/information on ingredients

# Substances Name Product identifier % Classification according to Regulation (EC) No. 1272/2008 [CLP] Betacarotene CAS-No.: 7235-40-7 EC-No.: 230-636-6 ≤ 100 Self-heat. 2, H252 Eye Irrit. 2, H319

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures	
4.1. Description of first aid measures	
First-aid measures general First-aid measures after inhalation	<ul> <li>In all cases of doubt, or when symptoms persist, seek medical attention.</li> <li>Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.</li> </ul>
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact	: Rinse immediately and thoroughly, pulling the eyelids well away from the eye (15 minutes minimum). Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.
4.2. Most important symptoms and effects,	both acute and delayed
Symptoms/effects after eye contact	: Causes serious eye irritation. Redness, pain.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures	
5.1. Extinguishing media	
Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.
Unsuitable extinguishing media	: Do not use a heavy water stream.

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5.2. Special hazards arising from the substance or mixture	
Hazardous decomposition products in case of fire	: Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.
5.3. Advice for firefighters	
Firefighting instructions Protection during firefighting	<ul> <li>Prevent fire fighting water from entering the environment.</li> <li>Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.</li> </ul>

SECTION 6: Accidental release measures	
6.1. Personal precautions, protec	tive equipment and emergency procedures
General measures	: Avoid contact with skin, eyes and clothing.
For non-emergency personnel	
Emergency procedures	: Evacuate unnecessary personnel.
For emergency responders	
Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
6.2. Environmental precautions	

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up	
For containment Methods for cleaning up	<ul> <li>Absorb with an inert material and place in an appropriate waste disposal container.</li> <li>Clean contaminated surfaces with an excess of water. Clean with the help of detergents.</li> </ul>
6.4. Reference to other sections	

See Section 13 for disposal information.

SECTION 7: Handling and storage		
7.1. Precautions for safe handling		
Precautions for safe handling Hygiene measures	<ul> <li>Avoid all unnecessary exposure. Ensure good ventilation of the work station.</li> <li>Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.</li> </ul>	
7.2. Conditions for safe storage, including any incompatibilities		
Storage conditions	: Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.	
Packaging materials	: Keep in original containers.	
7.3. Specific end use(s)		

No additional information available

# SECTION 8: Exposure controls/personal protection

## 8.1. Control parameters

No additional information available

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## 8.2. Exposure controls

## Appropriate engineering controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

## **Personal protection equipment**

#### Eye and face protection

#### Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

#### **Skin protection**

#### Skin and body protection: Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

#### Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

#### **Respiratory protection**

## **Respiratory protection:**

In case of dust formation use respirator with filter: P3

SECTION 9: Physical	and chemical	properties

## 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: brown-red. Brownish red.
Appearance	: Crystalline powder.
Molecular mass	: 536.9 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: > 174 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
рН	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: < 0.1 g/l
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: > 6.5
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

## 9.2. Other information

No additional information available

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SECTION 10: Stability and reactivity
10.1. Reactivity
Self-heating in large quantities; may catch fire.
10.2. Chemical stability
No additional information available
10.3. Possibility of hazardous reactions
No additional information available
10.4. Conditions to avoid
No additional information available
10.5. Incompatible materials
No additional information available
10.6. Hazardous decomposition products
No additional information available

# SECTION 11: Toxicological information

Acute toxicity (oral) Acute toxicity (dermal) Acute toxicity (inhalation)	<ul> <li>Not classified (Based on available data, the classification criteria are not met)</li> <li>Not classified (Lack of data)</li> <li>Not classified (Lack of data)</li> </ul>
Setacarotene (7235-40-7)	
LD50 oral rat	> 2000 mg/kg
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Causes serious eye irritation.
espiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Lack of data)
Reproductive toxicity	: Not classified (Lack of data)
TOT-single exposure	: Not classified (Lack of data)
TOT-repeated exposure : Not classified (Lack of data)	
spiration hazard	: Not classified (Lack of data)

## 11.2. Information on other hazards

No additional information available

# SECTION 12: Ecological information

12.1. Toxicity		
Hazardous to the aquatic environment, short-term : Not classified (Based on available data, the classification criteria are not met) (acute) Hazardous to the aquatic environment, long-term : Not classified (Based on available data, the classification criteria are not met) (chronic)		
Betacarotene (7235-40-7)		
LC50 - Fish [1]	> 1000 mg/l (96 Hours, Oncorhynchus mykiss (Rainbow trout))	
EC50 - Crustacea [1]	> 100 mg/l (48 Hours, Daphnia magna (Water flea)) (OECD 202 method)	

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Betacarotene (7235-40-7)		
ErC50 algae	231 mg/l (72 Hours, Desmodesmus subspicatus (Green algae)) (OECD 201 method)	
EIC50 aigae	231 mg/l (72 Hours, Desmodesmus subspicatus (Green aigae)) (OECD 201 method)	
12.2. Persistence and degradability		
Betacarotene (7235-40-7)		
Persistence and degradability	Not rapidly degradable	
12.3. Bioaccumulative potential		
Betacarotene (7235-40-7)		
Partition coefficient n-octanol/water (Log Pow)	> 6.5	
12.4. Mobility in soil		
No additional information available		
12.5. Results of PBT and vPvB assessment		
No additional information available		
12.6. Endocrine disrupting properties		
No additional information available		
12.7. Other adverse effects		
No additional information available		

# SECTION 13: Disposal considerations

13.1. Waste treatment methods

No additional information available

# SECTION 14: Transport information

n accordance with ADR / IMDG / IATA			
ADR	IMDG	ΙΑΤΑ	
14.1. UN number or ID number			
UN 3088	UN 3088	UN 3088	
14.2. UN proper shipping name	·		
SELF-HEATING SOLID, ORGANIC, N.O.S.	SELF-HEATING SOLID, ORGANIC, N.O.S.	Self-heating solid, organic, n.o.s.	
Transport document description			
UN 3088 SELF-HEATING SOLID, ORGANIC, N.O.S., 4.2, II, (D/E)	UN 3088 SELF-HEATING SOLID, ORGANIC, N.O.S., 4.2, II	UN 3088 Self-heating solid, organic, n.o.s., 4.2 II	
14.3. Transport hazard class(es)			
4.2	4.2	4.2	

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ADR	IMDG	IATA	
14.4. Packing group			
II	П	II	
14.5. Environmental hazards			
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No EmS-No. (Fire): F-A EmS-No. (Spillage): S-J	Dangerous for the environment: No	
No supplementary information available			
14.6. Special precautions for user			
Overland transport			
Classification code (ADR)	: S2		
Special provisions (ADR)	: 274		
Limited quantities (ADR)	: 0		
Excepted quantities (ADR)	: E2		
Packing instructions (ADR)	: P410, IBC06		
Mixed packing provisions (ADR)	: MP14		
Portable tank and bulk container instructions (ADR)			
Portable tank and bulk container special provisions (ADR) (ADR)	: TP33		
Tank code (ADR)	: SGAV		
Vehicle for tank carriage	: AT		
Transport category (ADR)	: 2		
Special provisions for carriage - Packages (ADR)	: : V1		
Hazard identification number (Kemler No.)	: 40		
Orange plates	40 3088		
Tunnel restriction code (ADR)	: D/E		
Transport by sea			
Special provisions (IMDG)	: 274		
Limited quantities (IMDG)	: 0		
Excepted quantities (IMDG)	: E2		
Packing instructions (IMDG)	· : P410		
Special packing provisions (IMDG)	: PP31		
IBC packing instructions (IMDG)	: IBC06		
IBC special provisions (IMDG)	: B21		
Tank instructions (IMDG)	: T3		
Tank special provisions (IMDG)	: TP33		
Stowage category (IMDG)	: C		
Properties and observations (IMDG)	: Liable to self-heating or spontaneous comb	pustion.	
Air transport			
PCA Excepted quantities (IATA)	: E2		
PCA Limited quantities (IATA)	: Forbidden		
PCA limited quantity max net quantity (IATA)	: Forbidden		
PCA packing instructions (IATA)	: 467		
PCA max net quantity (IATA)	: 15kg		
CAO packing instructions (IATA)	: 470		
CAO max net quantity (IATA)	: 50kg		
Special provisions (IATA)	: A3, A803		
ERG code (IATA)	: 4L		
14.7. Maritime transport in bulk according t	o IMO instruments		

## Not applicable

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## **SECTION 15: Regulatory information**

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

#### **EU-Regulations**

**REACH Annex XVII (Restriction List)** 

Not listed on REACH Annex XVII

## REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

#### **REACH Candidate List (SVHC)**

Not listed on the REACH Candidate List

#### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

#### Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

## Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

## Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.2. Chemical safety assessment

No additional information available

## **SECTION 16: Other information**

Indication of changes		
Section	Changed item	Comments
	Revision date	Added
	Supersedes version of	Added
1.1	EC-No.	Added
1.1	CAS-No.	Added
1.2	Restrictions on use	Modified
1.2	Use of the substance/mixture	Modified
1.2	Main use category	Removed
2.1	Adverse physicochemical, human health and environmental effects	Modified
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified
2.2	Hazard statements (CLP)	Modified
2.2	Signal word (CLP)	Modified
2.3	Other information	Added
4.1	First-aid measures after ingestion	Added
4.1	First-aid measures after inhalation	Added
4.1	First-aid measures general	Added

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Indication of changes		
Section	Changed item	Comments
4.1	First-aid measures after skin contact	Modified
4.1	First-aid measures after eye contact	Modified
4.2	Symptoms/effects after eye contact	Added
5.1	Unsuitable extinguishing media	Added
5.1	Suitable extinguishing media	Modified
5.2	Hazardous decomposition products in case of fire	Added
5.2	Fire hazard	Removed
5.3	Protection during firefighting	Added
5.3	Firefighting instructions	Modified
6.1	Protective equipment	Added
6.1	General measures	Added
6.1	Emergency procedures	Modified
6.2	Environmental precautions	Added
6.3	For containment	Added
6.3	Methods for cleaning up	Added
6.4	Reference to other sections (8, 13)	Added
7.1	Precautions for safe handling	Added
7.1	Hygiene measures	Added
7.2	Packaging materials	Added
7.2	Storage conditions	Added
7.3	Specific end uses	Removed
8.2	Eye protection	Added
8.2	Respiratory protection	Added
8.2	Hand protection	Modified
8.2	Appropriate engineering controls	Modified
8.2	Skin and body protection	Modified
9	Colour	Added
9	Appearance	Added
9	Molecular mass	Added
9	Melting point	Added
9	Partition coefficient n-octanol/water (Log Pow)	Added
10.1	Reactivity	Modified
10.3	Possibility of hazardous reactions	Removed
10.5	Incompatible materials	Removed
10.6	Hazardous decomposition products	Removed
11.1	LD50 oral rat	Added
12.1	Ecology - general	Removed

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Indication of changes		
Section	Changed item	Comments
12.1	LC50 - Fish [1]	Added
12.1	EC50 - Crustacea [1]	Added
12.1	ErC50 algae	Added

Full text of H- and EUH-statements:		
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
H252	Self-heating in large quantities; may catch fire.	
H319	Causes serious eye irritation.	
Self-heat. 2	Self-Heating Substances and Mixtures, Category 2	

Safety Data Sheet (SDS), EU

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