



## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 Date of issue: 9/25/2019 Version: 1.0

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

## 1.1. Product identifier

Product form : Substance Substance name : Cabazitaxel

IUPAC name : 7,10-dimethyl-docetaxel

 EC-No.
 : 680-632-7

 CAS-No.
 : 183133-96-2

 Product code
 : 58675245

 Formula
 : C45H57NO14

 Product group
 : Raw material

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

#### 1.2.1. Relevant identified uses

Main use category : Laboratory use, Industrial use, Professional use

Industrial/Professional use spec : For professional use only Use of the substance/mixture : For analytical purposes

Scientific research and development

Not for human consumption or veterinary purposes.

#### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

#### Supplier

Scafell Organics Molekula Ltd Lingfield Way Darlington - England

T +44 (0) 1949 823777 / +44 (0) 7590 545705

info@molekula.com / kbowen@molekula.com - www.molekula.com

## 1.4. Emergency telephone number

Emergency number : +44 (0) 7590 545705

# **SECTION 2: Hazards identification**

## 2.1. Classification of the substance or mixture

## Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral), Category 4 H302
Carcinogenicity, Category 2 H351
Reproductive toxicity, Category 2 H361fd

Full text of H statements : see section 16

#### Adverse physicochemical, human health and environmental effects

No additional information available

#### 2.2. Label elements

## Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)





GHS07

GHS08

Signal word (CLP) : Warning

Hazard statements (CLP) : H302 - Harmful if swallowed.

H351 - Suspected of causing cancer.

H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.

Precautionary statements (CLP) : P201 - Obtain special instructions before use.

P263 - Avoid contact during pregnancy and while nursing.

P280 - Wear protective gloves/protective clothing/eye protection/face protection. P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.

## 2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

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SECTION 3: Composition/information on ingredients				
3.1. Substances				
Name	Product identifier	%		
Cabazitaxel	(CAS-No.) 183133-96-2 (EC-No.) 680-632-7	100		

Full text of H-statements: see section 16

#### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

# 4.1. Description of first aid measures

First-aid measures general : If possible show this sheet, if not available show packaging or label. Never give anything by mouth to an unconscious person. Do not leave affected person unattended.

First-aid measures after inhalation : If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable

for breathing. Give oxygen or artificial respiration if necessary. If breathing difficulties

persist: Get medical advice/attention.

First-aid measures after skin contact : After contact with skin, take off immediately all contaminated clothing, and wash

immediately with plenty of water. Do not remove clothing if it sticks to the skin. If irritation

persists, consult a doctor.

First-aid measures after eye contact : Rinse immediately with plenty of water. Remove contact lenses, if present and easy to do.

Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Rinse mouth out with water. Do not induce vomiting. Get medical advice/attention.

## 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation : Inhalation may cause irritation (cough, short breathing, difficulty in breathing).

Symptoms/effects after skin contact : May cause moderate irritation, including burning sensation, tearing, redness or swelling.

Symptoms/effects after eye contact : May cause slight irritation. stinging. Redness, pain.

Symptoms/effects after ingestion : Harmful if swallowed. Symptoms of ingestion include drowsiness, weakness, headache,

dizziness, nausea, vomiting.

Chronic symptoms : Suspected of causing cancer. Suspected of damaging fertility. Suspected of damaging the

unborn child.

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

If exposed or concerned, get medical advice and attention.

#### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media : Dry powder. Sand. Water spray. Carbon dioxide. Foam.

Unsuitable extinguishing media : Do not use a heavy water stream.

## 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Carbon oxides (CO, CO2). Nitrogen oxides.

## 5.3. Advice for firefighters

Precautionary measures fire : Keep container tightly closed and away from heat, sparks and flame. Keep away from

combustible materials.

Firefighting instructions : Exercise caution when fighting any chemical fire. Use water spray or fog for cooling

exposed containers. Prevent fire fighting water from entering the environment.

Protection during firefighting : Wear recommended personal protective equipment. Use self-contained breathing

apparatus and chemically protective clothing.

Other information : Warn all persons of toxic hazard.

# **SECTION 6: Accidental release measures**

## 6.1. Personal precautions, protective equipment and emergency procedures

General measures : Isolate from fire, if possible, without unnecessary risk. Avoid dust formation. No flames, no

sparks. Eliminate all sources of ignition.

## 6.1.1. For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment.

Emergency procedures : Evacuate unnecessary personnel. Mark out the contaminated area with signs and prevent

access to unauthorized personnel. Do not touch or walk on the spilled product. Avoid

contact with skin, eyes and clothing.

Measures in case of dust release : Keep upwind. Avoid creating or spreading dust. Ventilate the area thoroughly, especially

low lying areas (basements, workpits etc).

## 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. Use self-contained

breathing apparatus and chemically protective clothing.

Emergency procedures : Ventilate area.

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## 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

#### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : On land, swe

: On land, sweep or shovel into suitable containers. Shovel or sweep up and put in a closed container for disposal.

#### 6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

## **SECTION 7: Handling and storage**

## 7.1. Precautions for safe handling

Precautions for safe handling

: Avoid creating or spreading dust. Avoid contact with skin, eyes and clothing. Do not handle until all safety precautions have been read and understood. Ensure that there is a suitable ventilation system. Do not handle in a confined space.

Hygiene measures

: Take off immediately all contaminated clothing and wash it before reuse. Contaminated work clothing should not be allowed out of the workplace. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke when using this product.

#### 7.2. Conditions for safe storage, including any incompatibilities

Technical measures

: Ensure adequate ventilation, especially in confined areas.

Storage conditions

: Keep only in the original container in a cool, well ventilated place away from : Heat

sources, Direct sunlight. Keep container closed when not in use.

Incompatible products

: Strong oxidizing agents.

Incompatible materials

: Sources of ignition. Direct sunlight. Heat sources.

Heat and ignition sources

: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No

smoking

Storage area

: Store at -20°C. Store in a dry place. Store in a closed container.

## 7.3. Specific end use(s)

For analytical purposes. Scientific research and development. Not for human consumption or veterinary purposes.

## **SECTION 8: Exposure controls/personal protection**

#### 8.1. Control parameters

No additional information available

## 8.2. Exposure controls

#### Appropriate engineering controls:

Handle in accordance with good industrial hygiene and safety procedures.

## Personal protective equipment:

Avoid all unnecessary exposure.

## Materials for protective clothing:

Wear suitable protective clothing, gloves and eye/face protection

#### Hand protection:

The protective gloves to be used must comply with the specifications of the regulation 2016/425 and the resultant standard EN 374

Туре	Material	Permeation	Thickness (mm)	Penetration	Standard
Disposable gloves	Butyl rubber	6 (> 480 minutes)	0.3		EN 374

## Eye protection:

Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure. Use eye protection according to EN 166, designed to protect against powders and dusts.

Туре	Use	Characteristics	Standard
Safety goggles, Face shield	Fine dust, Dust	tightly fitting safety goggles, With side shields	EN 166

## Skin and body protection:

Emergency safety showers should be available in the immediate vicinity of any potential exposure. Keep suitable chemically resistant protective clothing readily available for emergency use

Туре	Standard
Total impervious protective suits, gloves, and boots must be worn to prevent any contact with the product	EN ISO 13982

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## Respiratory protection:

Keep self contained breathing apparatus readily available for emergency use. Where exposure through inhalation may occur from use, respiratory protection equipment is recommended

Device	Filter type	Condition	Standard
Air-Purifying Respirator (APR), reusable	Type P3	Protection for Solid particles, Mist formation, Dust protection	EN 14387

#### Other information:

Do not eat, drink or smoke during use.

## SECTION 9: Physical and chemical properties

## 9.1. Information on basic physical and chemical properties

Physical state : Solid Appearance : Powder. : 835.93 g/mol Molecular mass Colour : White to off-white. Odour : No data available. Odour threshold · No data available pН : No data available Relative evaporation rate (butylacetate=1) : No data available : No data available Melting point Freezing point : No data available Boiling point : No data available Flash point No data available Auto-ignition temperature : No data available Decomposition temperature : No data available Flammability (solid, gas) No data available Vapour pressure : No data available Relative vapour density at 20 °C : No data available Relative density : No data available Solubility : No data available Log Pow : 3.3 : No data available Viscosity, kinematic : No data available Viscosity, dynamic : No data available Explosive properties Oxidising properties : No data available

## 9.2. Other information

No additional information available

# **SECTION 10: Stability and reactivity**

#### 10.1. Reactivity

**Explosive limits** 

The product is non-reactive under normal conditions of use, storage and transport.

## 10.2. Chemical stability

Stable under normal conditions of use.

#### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

## 10.4. Conditions to avoid

Protect from sunlight. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

: No data available

#### 10.5. Incompatible materials

Strong oxidizers.

## 10.6. Hazardous decomposition products

No hazardous decomposition products known at room temperature. Thermal decomposition generates: Carbon oxides (CO, CO2). Nitrogen oxides.

#### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

Acute toxicity (oral) : Oral: Harmful if swallowed

Acute toxicity (dermal) : Not classified Acute toxicity (inhalation) : Not classified

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Cabazitaxel (183133-96-2)	
LD50 oral rat	500 mg/kg
Skin corrosion/irritation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Carcinogenicity	: Suspected of causing cancer.
Additional information	: Based on available data, the classification criteria are not met
Reproductive toxicity	: Suspected of damaging fertility. Suspected of damaging the unborn child.
Additional information	: Based on available data, the classification criteria are not met
STOT-single exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-repeated exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION	12: Ecol	ogical in	formation
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Acute aquatic foxicity : Not classified Chronic aquatic toxicity : Not classified

# 12.2. Persistence and degradability

## Cabazitaxel (183133-96-2)

Persistence and degradability No data available.

## 12.3. Bioaccumulative potential

## Cabazitaxel (183133-96-2)

Log Pow 3.3

Bioaccumulative potential No data available.

# 12.4. Mobility in soil

No additional information available

## 12.5. Results of PBT and vPvB assessment

# Cabazitaxel (183133-96-2)

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

## 12.6. Other adverse effects

Additional information : Avoid release to the environment.

## **SECTION 13: Disposal considerations**

## 13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

# **SECTION 14: Transport information**

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated

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14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

## 14.6. Special precautions for user **Overland transport**

Not regulated

## Transport by sea

Not regulated

#### Air transport

Not regulated

#### Inland waterway transport

Not regulated

#### Rail transport

Not regulated

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

Not applicable

## **SECTION 15: Regulatory information**

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

## 15.1.1. EU-Regulations

No REACH Annex XVII restrictions Cabazitaxel is not on the REACH Candidate List Directive 2012/18/EU (SEVESO III)

## 15.1.2. National regulations

No additional information available

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier

#### **SECTION 16: Other information**

Data sources REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and

repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Carc. 2 Carcinogenicity, Category 2	
Repr. 2 Reproductive toxicity, Category 2	
H302	Harmful if swallowed.
H351	Suspected of causing cancer.
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.	

## SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.