

# Cetomacrogol emulsifying wax

## Safety Data Sheet

**248606**

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Version: 3.0

Date of issue: 13/08/2012 Revision date 03/10/2018

Supersedes 07/03/2017

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

#### 1.1. Product identifier

Product form : Mixture  
 Product name : Cetomacrogol emulsifying wax  
 Product code : 248606  
 Product group : Raw material  
 Other means of identification : Non-ionic Emulsifying Wax consisting of C16-C18 alcohols.

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

##### 1.2.1. Relevant identified uses

Main use category : Pharmaceutical  
 Function or use category : Raw material

##### 1.2.2. Uses advised against

No additional information available

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

##### Supplier

Duchefa Farma BV  
 A. Hofmanweg 71  
 2031BH Haarlem - The Netherlands  
 T +31(0)23-5319093  
[farma@duchefa.nl](mailto:farma@duchefa.nl) - [www.duchefa-farma.com](http://www.duchefa-farma.com)

#### 1.4. Emergency telephone number

Emergency number : Supplier contact information:  
 +31(0)23-5319093 (M-F 09:00-17:00)  
 +31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	+44 20 7188 7188	

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

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

No additional information available

#### 2.2. Label elements

According to EC directives or the corresponding national regulations there is no labelling obligation for this product.

## 2.3. Other hazards

No additional information available

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Comments : Mixture of Alkyl polyglycol ether C16-C18

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation : Not applicable.  
First-aid measures after skin contact : Rinse with plenty of water.  
First-aid measures after eye contact : Rinse immediately with plenty of water. Seek medical advice.  
First-aid measures after ingestion : Rinse mouth. Drink 200-300 ml of water.

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

Symptoms/effects : No significant symptoms are expected due to the non-classification of the product.

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

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : dry chemical powder. Water spray. Alcohol resistant foam.  
Unsuitable extinguishing media : Carbon dioxide (CO<sub>2</sub>).

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

Explosion hazard : Product is not explosive.  
Hazardous decomposition products in case of fire : Carbon oxides (CO, CO<sub>2</sub>).

### 5.3. Advice for firefighters

Firefighting instructions : Prevent fire fighting water from entering the environment.  
Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

## SECTION 6: Accidental release measures

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

#### 6.1.1. For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment.

### 6.1.2. For emergency responders

Protective equipment : Wear proper protective equipment.

### 6.2. Environmental precautions

Prevent product from entering drains.

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

For containment : Sweeping or shovelling without dust for disposal.

Methods for cleaning up : Residue may be washed down with water.

### 6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection".

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

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

Storage conditions : Store in dry, well-ventilated area. Keep container tightly closed.

Storage temperature : 15 - 25 °C

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

#### Appropriate engineering controls:

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

#### Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

#### Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

#### Skin and body protection:

Wear suitable protective clothing.

#### Respiratory protection:

Respiratory protection according to European standard EN 14387 or equivalent. Dustmask with filtertype P1

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state : Solid

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Appearance	: Pellets/tablets.
Colour	: White.
Odour	: Characteristic.
Odour threshold	: No data available
pH	: 6 - 8
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: 48 - 53 °C
Boiling point	: No data available
Flash point	: 159 - 161 °C
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
Density	: 0.8 - 0.82 g/cm <sup>3</sup> 60°C
Solubility	: Emulsifiable.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

### 9.2. Other information

Other properties : Bulk density: 0.910 g/cm<sup>3</sup> (20°C).

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No dangerous reactions known under normal conditions of use.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

None under normal conditions.

### 10.4. Conditions to avoid

heat. High temperature. Moisture.

### 10.5. Incompatible materials

No additional information available

### 10.6. Hazardous decomposition products

No additional information available

**SECTION 11: Toxicological information****11.1. Information on toxicological effects**

Acute toxicity : Not classified

Cetomacrogol emulsifying wax	
LD50 oral rat	> 5000 mg/kg
Irritation	: Not classified pH: 6 - 8
Corrosivity	: Not classified pH: 6 - 8
Sensitisation	: Not classified
Repeated dose toxicity	: Not classified
Carcinogenicity	: Not classified
Mutagenicity	: Not classified
Toxicity for reproduction	: Not classified

**SECTION 12: Ecological information****12.1. Toxicity**

Cetomacrogol emulsifying wax	
LC50 fish 1	10 - 100 mg/l
EC50 other aquatic organisms 1	> 100 mg/l

**12.2. Persistence and degradability**

Cetomacrogol emulsifying wax	
Persistence and degradability	Biodegradable.
Biodegradation	> 90 %

**12.3. Bioaccumulative potential**

Cetomacrogol emulsifying wax	
Bioaccumulative potential	No bioaccumulation data available.

**12.4. Mobility in soil**

No additional information available

**12.5. Results of PBT and vPvB assessment**

No additional information available

**12.6. Other adverse effects**

No additional information available

**SECTION 13: Disposal considerations****13.1. Waste treatment methods**

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

Waste treatment methods : Avoid release to the environment.

**SECTION 14: Transport information**

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

ADR	IATA
<b>14.1. UN number</b>	
Not applicable	Not applicable

ADR	IATA
<b>14.2. UN proper shipping name</b>	
Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>	
Not applicable	Not applicable
Not applicable	Not applicable
<b>14.4. Packing group</b>	
Not applicable	Not applicable
<b>14.5. Environmental hazards</b>	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

## 14.6. Special precautions for user

### - Overland transport

No data available

### - Air transport

No data available

## 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

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

## SECTION 16: Other information

Indication of changes:

1.4	Emergency telephone	Modified	Added additional information
2	Classification (DSD/DPD)	Removed	Obsolete
2.2	Hazard pictograms (CLP)	Removed	GHS05 deleted
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods

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IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources : Supplier. 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.

SDS EU (REACH Annex II) Version 2018

*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*