

## Safety data sheet according to 1907/2006/EC, Article 31

Printing date: 11.07.2012

Version: 2

Revision: 11.07.2012

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

**1.1 Product identifier****Trade name:** WITEPSOL H 15**Registration number:**

This substance has (All substances contained in this preparation have) been pre-registered according to regulation (EC) No. 1907/2006 in its current version.

A registration is intended.

**1.2 Relevant identified uses of the substance or mixture and uses advised against: -****Uses advised against: -****Application of the substance / the preparation:**

Raw material for industrial applications

Pharmaceutical raw material

**1.3 Details of the supplier of the safety data sheet****Supplier/Manufacturer:**

CREMER OLEO GmbH & Co. KG

Glockengiesserwall 3

20095 Hamburg

Germany

Tel.: +49-40-32011-0

Fax: +49-40-321757

**Email competent person:** quality47@cremer-gruppe.com**Information department:** See supplier/manufacturer**1.4 Emergency telephone number:**

GIZ-Nord, Göttingen, Germany

+49 551 19240

### SECTION 2: Hazards identification

**2.1 Classification of the substance or mixture****Classification according to Directive 67/548/EEC or Directive 1999/45/EC** not applicable**Information concerning particular hazards for human and environment:**

The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

**Classification system:**

The classification was made according to the latest editions of the EC-lists and expanded using company data and specialized literature.

**Additional information:** Product forms slippery surface when combined with water.**2.2 Label elements****Labelling according to EU guidelines:**

The product is not subject to identification regulations under EC Directives and the Ordinance on Hazardous Materials (GefStoffV). Observe the general safety regulations when handling chemicals

**2.3 Other hazards****Results of PBT and vPvB assessment****PBT:** Not applicable**vPvB:** Not applicable

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### SECTION 3: Composition/information on ingredients

#### · 3.2 Chemical characterization: Mixtures

##### · Description:

Mixture based on:  
Glycerides, C12-18-  
CAS: 67701-26-2  
REACH-Nr. 01-2119485904-26-0000

##### · Dangerous components: Void

· **Additional information:** For the wording of the listed risk phrases refer to section 16.

### SECTION 4: First aid measures

#### · 4.1 Description of first aid measures

· **General information:** If symptoms persist or in case of doubt, seek medical advice.

· **After inhalation:** Supply fresh air; consult a doctor in case of pain.

##### · After skin contact:

Rinse with plenty of water.  
If symptoms persist, consult a doctor.

##### · After eye contact:

Rinse opened eye for several minutes under running water.  
If symptoms persist, consult a doctor.

##### · After swallowing:

Seek medical treatment.  
Rinse mouth with water.  
Do not induce vomiting.  
Unless instructed explicitly by medical staff.  
Never give anything by mouth to an unconscious person.

· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed** Symptomatic treatment

### SECTION 5: Firefighting measures

#### · 5.1 Extinguishing media

##### · Suitable extinguishing agents:

Fire-extinguishing powder  
Carbon dioxide (CO<sub>2</sub>)  
Foam

Use fire fighting measures that suit the environment.

· **For safety reasons unsuitable extinguishing agents:** High volume water jet

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

In case of fire, the following can be released:

Carbon monoxide (CO)  
Carbon dioxide (CO<sub>2</sub>)

#### · 5.3 Advice for firefighters

· **Protective equipment:** Wear self-contained respiratory protective device.

· **Additional information:** Cool endangered receptacles with water spray.

### SECTION 6: Accidental release measures

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

Wear protective clothing.  
Product forms slippery surface when combined with water.

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- Particular danger of slipping on leaked/spilled product.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:**  
Pick up mechanically.  
Make sure to recycle or dispose of in suitable receptacles.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about protection against explosions and fires:**



Keep ignition sources away - Do not smoke.

Observe the general rules of industrial fire protection.

- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Keep receptacle well sealed and storage at a well-ventilated area.
- **Information about storage in one common storage facility:**  
Store away from foodstuffs.  
Store away from feed.
- **Further information about storage conditions:** None
- **Storage class:** 11 Combustible solids
- **7.3 Specific end use(s)** No further relevant information available

### SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **8.1 Control parameters**
- **Components with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

#### · **DNELs**

Abbreviations:

In = Industrial

Prof = Professional

Cons = Consumer

LLE = Long term, local effects

LSE = Long term, systemic effects

SLE = Short term, local effects

SSE = Short term, systemic effects

#### · **67701-26-2 Glycerides, C12-18**

Oral DNEL/Cons/LSE 17.115 mg/kg bw/day (human)

Dermal DNEL/Cons/LSE 17.115 mg/kg bw/day (human)

DNEL/In/LSE 34.23 mg/kg bw/day (human)

Inhalative DNEL/Cons/LSE 59.53 mg/m<sup>3</sup> (human)

DNEL/In/LSE 241.41 mg/m<sup>3</sup> (human)

- **PNECs** No long term toxicity to aquatic organisms expected. Therefore no derivation of PNEC.

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- **Additional information:** The lists that were valid during the creation were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures should be adhered to when handling chemicals.  
Wash hands before breaks and at the end of work.  
Use skin protection cream for skin protection.
- **Breathing equipment:**  
Not necessary if room is well-ventilated  
At formation of dust:  
Short term filter device:  
Filter P1  
Filter P2
- **Protection of hands:**  
Protective gloves  
After use of gloves apply skin-cleaning agents and skin cosmetics.  
The glove material has to be impermeable and resistant to the product/substance/preparation.  
Selection of the glove material in consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves:**  
The selection of suitable gloves depends upon the material, and also upon the quality of the gloves. The degree of protection will vary from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material:**  
The exact penetration time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **For the permanent contact gloves made of the following materials are suitable:**  
Nitrile rubber, NBR  
(Thickness: 0.35 mm; Permeation time:  $\geq$  480 minutes)  
Butyl rubber, BR  
(Thickness: 0.5 mm; Permeation time:  $\geq$  480 Minuten)
- **Eye protection:** Safety glasses
- **Body protection:** Protective work clothing

## SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information:**
- **Appearance:**
  - **Form:** Solid material.  
Pellets
  - **Colour:** White
  - **Odour:** Odourless
  - **Odour threshold:** Not applicable
- **pH-value:** Not applicable
- **Change in condition:**
  - **Melting point/Melting range:** ~31-38°C
  - **Boiling point/Boiling range:** Not determined
- **Flash point:** > 200°C (DIN ISO 2592)
- **Flammability (solid, gaseous):** Not determined
- **Ignition temperature:** Not determined
- **Decomposition temperature:** Not determined

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· <b>Self ignition temperature:</b>	Product is not self-igniting.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not applicable
<b>Upper:</b>	Not applicable
· <b>Vapour pressure:</b>	Not applicable
· <b>Density:</b>	~0.95 g/cm <sup>3</sup>
· <b>Relative density:</b>	Not determined
· <b>Vapour density:</b>	Not applicable
· <b>Evaporation rate:</b>	Not applicable
· <b>Solubility in / Miscibility with Water:</b>	Practically insoluble
· <b>Partition coefficient (n-octanol/water):</b>	Not determined
· <b>Viscosity:</b>	
<b>dynamic:</b>	Not applicable
<b>kinematic:</b>	Not applicable
· <b>9.2 Other information</b>	No further relevant information available

## SECTION 10: Stability and reactivity

- **10.1 Reactivity**
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
To avoid thermal decomposition do not overheat.  
No decomposition if used and stored according to specifications
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid**  
Strong heating  
Dirt  
Chemical contamination  
Sunlight, UV or ionizing radiation
- **10.5 Incompatible materials:** No further relevant information available
- **10.6 Hazardous decomposition products:**  
No hazardous decomposition products if instructions for storage and handling are followed

## SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:**
- **LD/LC50 values that are relevant for classification:**  
The product itself has not been tested. Information is based on products of similar structure and composition.  
**67701-26-2 Glycerides, C12-18**  
Oral LD<sub>50</sub> > 2000 mg/kg (rat) (OECD 401)  
Dermal LD<sub>50</sub> > 2000 mg/kg (rat)  
Literature  
Inhalative LC<sub>50</sub>/6h > 1.86 mg/l (rat) (OECD 403)  
Literature
- **Primary irritant effect:**
- **on the skin:** Skin irritation test (rabbit): no irritation

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- **on the eye:** Skin irritation test (rabbit): no irritation
- **Sensitization:**  
No sensitization species: guinea pig OECD 406  
(Buehler Test)
- **Other information (about experimental toxicology):**
- **Carcinogenic, mutagenic effects and adverse effects on reproduction:**  
The product itself has not been tested. Information is based on products of similar structure and composition. Presently available data show no carcinogenic, mutagenic or teratogenic effects.
- **67701-26-2 Glycerides, C12-18**  
Oral NOAEL 1000 mg/kg bw/day (rat) (OECD422)  
NOAEL (F1) 1000 mg/kg bw/day (rat) (OECD 422)  
49 d Literature, substance: glycerides, C8-18 and C18 unsaturated mono- and di-, acetate  
NOAEL (P) 1000 mg/kg bw/day (rat) (OECD 422)  
49 d Literature, substance: glycerides, C8-18 and C18 unsaturated mono- and di-, acetate
- **Subacute to chronic toxicity:**
- **STOT-single exposure** No classification
- **STOT-repeated exposure:** No classification
- **Aspiration hazard** Not relevant
- **Additional toxicological information:**  
The toxicological information refers to the main component.  
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:  
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
- **Toxicokinetics, metabolism and distribution:** Fatty acid glycerides are metabolized or stored in adipose tissue.
- **Repeated dose toxicity:**  
The product itself has not been tested. Information is based on products of similar structure and composition.
- **67701-26-2 Glycerides, C12-18**  
Oral NOAEL 1000 mg/kg/day (rat) (OECD 422)  
5000 mg/kg bw/d (rat) (OECD 408)  
Literature; test substance: castor oil

## SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No harmful effect on fish, daphnia and algae up to its limit of solubility.
- **12.2 Persistence and degradability** Easily biodegradable
- **Other information:**  
Biological degradation: >60% after 28 days  
OECD 301 F  
In analogy to similar product
- **Behaviour in environmental systems:**
- **Components:**  
Water:  
Slow evaporation  
Soil:  
strong Adsorption on the ground
- **12.3 Bioaccumulative potential**  
No bioaccumulation to be expected  
Conclusion by analogy
- **12.4 Mobility in soil** strong Adsorption on the ground
- **Adsorption coefficient Koc:**  
log Koc 9  
(calculated)

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- **Additional ecological information:**
- **General notes:**  
The declaration of the ecology refers to the main component.  
Generally not hazardous for water  
According to appendix 4 of VwVwS dated 27.7.2005 (German regulation)
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable
- **vPvB:** Not applicable
- **12.6 Other adverse effects** No further relevant information available

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation:** Adhering to the official regulations, it can be disposed of in an appropriate incinerator.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

· <b>14.1 UN-Number</b> · <b>ADR, ADN, IMDG, IATA</b>	Void
· <b>14.2 UN proper shipping name</b> · <b>ADR, ADN, IMDG, IATA</b>	Void
· <b>14.3 Transport hazard class(es)</b> · <b>ADR, ADN, IMDG, IATA</b> · <b>Class</b>	Void
· <b>14.4 Packing group</b> · <b>ADR, IMDG, IATA</b>	Void
· <b>14.5 Environmental hazards:</b> · <b>Marine pollutant:</b>	No
· <b>14.6 Special precautions for user</b>	Not applicable
· <b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations**
- **Water hazard class:** Generally not hazardous for water
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

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· **Reasons for amendments:**

General revision

Data on components

· **Replaces version dated:** 04.04.2012

· **Department issuing MSDS:**

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