

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

Printing date: 26.07.2017

Version: 1.02

Revision: 26.07.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name:** **WITEPSOL® H 35****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: -**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:**IOI Oleo GmbH
Arthur-Imhausen Str. 92
D-58453 Witten

Tel.: ++49-40-280031-0

Email competent person: MSDS@ioioleo.de**Information department:** See supplier/manufacturer**1.4 Emergency telephone number:**National Poison Information Service (NPIS)
24 hour national number professionals only
0844 892 0111National Health Service (NHS)
24 hour national number consumer
England and Scotland: 111
Wales: 0845 46 47
Northern Ireland: call your local General Practitioner

Call 999 if there is a life-threatening incident.

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008** The product is not classified according to the CLP regulation.**Additional information:** Product forms slippery surface when combined with water.**2.2 Label elements****Labelling according to Regulation (EC) No 1272/2008** Void**Hazard pictograms** Void**Signal word** Void**Hazard statements** Void**2.3 Other hazards****Results of PBT and vPvB assessment****PBT:** Not applicable**vPvB:** Not applicable**SECTION 3: Composition/information on ingredients****3.2 Chemical characterisation: Mixtures****Description:**

Mixture based on:

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

- **Dangerous components:** Void
- **Additional information:** For the wording of the listed hazard 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:**
Rinse mouth with water.
Seek medical treatment.
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 (CO₂)
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 (CO₂)
- **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.
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.

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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 properly.
- 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 section 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 ³ (human)
	DNEL/In/LSE	241.41 mg/m ³ (human)

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

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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/freezing point: ~31-38 °C

Initial boiling point and boiling range: Not determined

· Flash point: > 200 °C (DIN ISO 2592)

· Flammability (solid, gas): Not determined

· Ignition temperature: Not determined

· Decomposition temperature: Not determined

· Self ignition temperature: Product is not self-igniting.

· Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

Lower: Not applicable

Upper: Not applicable

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· Vapour pressure:	Not applicable
· Density:	~0.95 g/cm ³
· Relative density:	Not determined
· Vapour density:	Not applicable
· Evaporation rate:	Not applicable
· Solubility in / Miscibility with Water:	Practically insoluble
· Partition coefficient: n-octanol/water:	Not determined
· Viscosity: dynamic:	Not applicable
kinematic:	Not applicable
· 9.2 Other information	No further relevant information available

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available
- **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** Based on available data, the classification criteria are not met.
- **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 LD₅₀ > 2000 mg/kg (rat) (OECD 401)
Dermal LD₅₀ > 2000 mg/kg (rat)
Literature
Inhalative LC₅₀/6h > 1.86 mg/l (rat) (OECD 403)
Literature
- **Primary irritant effect:**
- **Skin corrosion/irritation** Skin irritation test (rabbit): no irritation
- **Serious eye damage/irritation** Skin irritation test (rabbit): no irritation
- **Respiratory or skin sensitisation**
No sensitisation species: guinea pig OECD 406
(Buehler Test)
- **Additional toxicological information:** The toxicological information refers to the main component.
- **Toxicokinetics, metabolism and distribution:** Fatty acid glycerides are metabolized or stored in adipose tissue.

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- **Repeated dose toxicity:**
The product itself has not been tested. Information is based on products of similar structure and composition.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction):**
- **Germ cell mutagenicity**
The product itself has not been tested. Information is based on products of similar structure and composition.
No mutagenic effects
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity**
No classification
- **67701-26-2 Glycerides, C12-18**
Oral NOAEL 1000 mg/kg bw/day (rat) (OECD 422)
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
- **STOT-single exposure** No classification
- **STOT-repeated exposure**
No classification
- **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
- **Aspiration hazard** Not relevant

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** Readily 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 to soil
- **12.3 Bioaccumulative potential**
No bioaccumulation to be expected
Conclusion by analogy
- **12.4 Mobility in soil** strong adsorption to soil
- **Adsorption coefficient K_{oc}:**
log K_{oc} 9
(calculated)
- **Additional ecological information:**
- **General notes:**
Generally not hazardous for water
According to appendix 4 of VwVwS dated 17.05.1999 (German regulation)
The declaration of the ecology refers to the main component.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable
- **vPvB:** Not applicable

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- **12.6 Other adverse effects** No further relevant information available

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation:**
Must be recycled or disposed of according to the regulations. Waste has to be classified according to the European Waste Catalogue based on the identification of the waste generating source.
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

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

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- Directive 2012/18/EU
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **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.

- **Reasons for amendments:** Layout
- **Replaces version dated:** 13.05.2016

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· **Department issuing SDS:**

KFT Chemieservice GmbH
Im Leuschnerpark. 3 64347 Griesheim
Postfach 1451 64345 Griesheim
Germany

Phone: +49 6155 8981 400 Fax: +49 6155 8981 500

Safety Data Sheet Service: +49 6155 8981 522

· **Contact:** Dr. Rebecca Hiltrop

· **Abbreviations and acronyms:**

ICAO: International Civil Aviation Organisation

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

· *** Data compared to the previous version altered.**

Changes have been made to sections marked with a *, as compared to the previous version.