

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Product form : Substance
Trade name : Witepsol® E 76
Chemical name : Glycerides, C12-18
EC-No. : 266-944-2
CAS-No. : 67701-26-2
REACH registration No : 01-2119485904-26-0000

1.2. Relevant identified uses of the substance or mixture and uses advised against**1.2.1. Relevant identified uses**

Use of the substance/mixture : Industrial use
Raw material
Pharmaceutical industry

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet**Supplier**

IOI Oleo GmbH
Arthur-Imhausen-Str. 92
D-58453 Witten - Germany
T +49 40 280031-0

Email competent person

MSDS@ioioleo.de

1.4. Emergency telephone number

Emergency number : National 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 [CLP]**

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements**Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

No labelling applicable

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

Witepsol® E 76

Safety Data Sheet

A safety data sheet is not required for this product in accordance with national legal requirements. This document has been created on a voluntary basis following the format of the safety data sheet.

SECTION 3: Composition/information on ingredients

3.1. Substances

| Name | Product identifier | % |
|--------------------|--|---|
| Glycerides, C12-18 | (CAS-No.) 67701-26-2 (EC-No.) 266-944-2 (REACH-no) 01-2119485904-26-0000 | - |

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

| | |
|---------------------------------------|--|
| First-aid measures general | : In all cases of doubt, or when symptoms persist, seek medical attention. |
| First-aid measures after inhalation | : Remove person to fresh air and keep comfortable for breathing. |
| First-aid measures after skin contact | : Wash skin with plenty of water. |
| First-aid measures after eye contact | : Rinse eyes with water as a precaution. |
| First-aid measures after ingestion | : Call a poison center or a doctor if you feel unwell. |

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

No additional information available

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 | : Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. |
| Unsuitable extinguishing media | : Strong water jet. |

5.2. Special hazards arising from the substance or mixture

| | |
|--|---|
| Hazardous decomposition products in case of fire | : Toxic fumes may be released. Carbon monoxide. Carbon dioxide. |
|--|---|

5.3. Advice for firefighters

| | |
|--------------------------------|--|
| Protection during firefighting | : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing. |
| Other information | : Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations. |

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

| | |
|----------------------|----------------------------|
| Emergency procedures | : Ventilate spillage area. |
|----------------------|----------------------------|

6.1.2. 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.

6.3. Methods and material for containment and cleaning up

| | |
|-------------------------|---|
| Methods for cleaning up | : Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal. |
| Other information | : Disposal must be done according to official regulations. |

Witepsol® E 76

Safety Data Sheet

A safety data sheet is not required for this product in accordance with national legal requirements. This document has been created on a voluntary basis following the format of the safety data sheet.

6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.
Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

| | |
|--|---|
| Glycerides, C12-18 (67701-26-2) | |
| United Kingdom - Occupational Exposure Limits | |
| | Observe general threshold limit for dust. |

| | |
|--|-----------------------------|
| Glycerides, C12-18 (67701-26-2) | |
| DNEL/DMEL (Workers) | |
| Long-term - systemic effects, dermal | 34.23 mg/kg bodyweight/day |
| Long-term - systemic effects, inhalation | 241.41 mg/m ³ |
| DNEL/DMEL (General population) | |
| Long-term - systemic effects, oral | 17.115 mg/kg bodyweight/day |
| Long-term - systemic effects, inhalation | 59.53 mg/m ³ |
| Long-term - systemic effects, dermal | 17.115 mg/kg bodyweight/day |

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Hand protection:

In case of repeated or prolonged contact wear gloves. EN 374. Nitrile rubber. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

Eye protection:

In case of dust production: protective goggles. EN 166

Skin and body protection:

Wear suitable protective clothing. EN ISO 13982. EN ISO 13688

Witepsol® E 76

Safety Data Sheet

A safety data sheet is not required for this product in accordance with national legal requirements. This document has been created on a voluntary basis following the format of the safety data sheet.

Respiratory protection:

Not required for normal conditions of use. Dust formation: dust mask. EN 143. Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust.

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---|--------------------------------|
| Physical state | : Solid |
| Appearance | : Pellet. |
| Colour | : white. |
| Odour | : odourless. |
| Odour threshold | : No data available |
| pH | : No data available |
| pH solution | : No data available |
| Relative evaporation rate (butylacetate=1) | : Not applicable |
| Melting point | : 37 – 39 °C |
| Freezing point | : Not applicable |
| Boiling point | : No data available |
| Flash point | : > 200 °C (DIN ISO 2592) |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Flammability (solid, gas) | : No data available |
| Vapour pressure | : Not applicable |
| Relative vapour density at 20 °C | : Not applicable |
| Relative density | : No data available |
| Density | : ≈ 0.95 g/cm ³ |
| Solubility | : Water: practically insoluble |
| Partition coefficient n-octanol/water (Log Pow) | : No data available |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : Not applicable |
| Explosive properties | : Product is not explosive. |
| Oxidising properties | : Non oxidizing. |
| Explosive limits | : No data available |

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

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

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Witepsol® E 76

Safety Data Sheet

A safety data sheet is not required for this product in accordance with national legal requirements. This document has been created on a voluntary basis following the format of the safety data sheet.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

| | |
|-----------------------------|--|
| Acute toxicity (oral) | : Not classified (Based on available data, the classification criteria are not met) |
| Acute toxicity (dermal) | : Not classified (Based on available data, the classification criteria are not met) |
| Acute toxicity (inhalation) | : Not classified. (Based on available data, the classification criteria are not met) |

| Glycerides, C12-18 (67701-26-2) | |
|---|---|
| LD50 oral rat | > 2000 mg/kg bodyweight (OECD 401 method) |
| LD50 dermal rat | > 2000 mg/kg bodyweight (79/831/EWG, Annex V, Part B) |
| LC50 inhalation rat (Dust/Mist - mg/l/4h) | > 1.86 mg/l/4h (Maximum concentration; (OECD 403 method)) |

| | |
|-----------------------------------|---|
| Skin corrosion/irritation | : Not classified (Based on available data, the classification criteria are not met) |
| Serious eye damage/irritation | : Not classified (Based on available data, the classification criteria are not met) |
| Respiratory 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 (Based on available data, the classification criteria are not met) |

Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)

STOT-single exposure : Not classified (Based on available data, the classification criteria are not met)

STOT-repeated exposure : Not classified (Based on available data, the classification criteria are not met)

| Glycerides, C12-18 (67701-26-2) | |
|---------------------------------|---|
| NOAEL (oral, rat, 90 days) | ≈ 5000 mg/kg bodyweight/day (OECD 408 method) |
| Aspiration hazard | : Not classified (Not relevant) |

SECTION 12: Ecological information

12.1. Toxicity

| | |
|---|--|
| Ecology - water | : Due to the consistency along with the low water solubility of the product a bioavailability is unlikely. |
| Hazardous to the aquatic environment, short-term (acute) | : Not classified (Based on available data, the classification criteria are not met) |
| Hazardous to the aquatic environment, long-term (chronic) | : Not classified (Based on available data, the classification criteria are not met) |

| Glycerides, C12-18 (67701-26-2) | |
|---------------------------------|---|
| LC50 fish 1 | > 10000 mg/l (96 h; Danio rerio; ISO 7346-1) |
| EC50 Daphnia 1 | > 100 mg/l (48 h; Daphnia magna; EU Method C.2) |
| ErC50 (algae) | > 100 mg/l (72 h; Desmodesmus subspicatus; EU Method C.3) |

12.2. Persistence and degradability

| Glycerides, C12-18 (67701-26-2) | |
|---------------------------------|---------------------------------|
| Persistence and degradability | Readily biodegradable. |
| Biodegradation | 79 % (28 d; (OECD 301F method)) |

12.3. Bioaccumulative potential

| Glycerides, C12-18 (67701-26-2) | |
|---------------------------------|---------------------------|
| Bioaccumulative potential | Bioaccumulation unlikely. |

Witepsol® E 76

Safety Data Sheet

A safety data sheet is not required for this product in accordance with national legal requirements. This document has been created on a voluntary basis following the format of the safety data sheet.

12.4. Mobility in soil

| Glycerides, C12-18 (67701-26-2) | |
|---|---|
| Partition coefficient n-octanol/water (Log Koc) | 9 Quantitative structure-activity relationship (QSAR) |
| Ecology - soil | Adsorbs into the soil. |

12.5. Results of PBT and vPvB assessment

| Glycerides, C12-18 (67701-26-2) | |
|--|--|
| 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

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.

Product/Packaging disposal recommendations : Recycle or dispose of in compliance with current legislation.

SECTION 14: Transport information

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

| ADR | IMDG | IATA | ADN | RID |
|---|----------------|----------------|----------------|----------------|
| 14.1. UN number | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| 14.2. UN proper shipping name | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| 14.3. Transport hazard class(es) | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| 14.4. Packing group | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| 14.5. Environmental hazards | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| No supplementary information available | | | | |

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Witepsol® E 76

Safety Data Sheet

A safety data sheet is not required for this product in accordance with national legal requirements. This document has been created on a voluntary basis following the format of the safety data sheet.

Rail transport

Not applicable

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

Glycerides, C12-18 is not on the REACH Candidate List

Glycerides, C12-18 is not on the REACH Annex XIV List

Witepsol® E 76 is not subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Witepsol® E 76 is not subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Other information, restriction and prohibition regulations : A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on a voluntary basis.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

| Indication of changes: | | | |
|------------------------|---------------|----------|----------|
| General revision. | | | |
| Section | Changed item | Change | Comments |
| 9.1 | Melting point | Modified | |

| Abbreviations and acronyms: | |
|-----------------------------|---|
| ADN | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| ATE | Acute Toxicity Estimate |
| BCF | Bioconcentration factor |
| CLP | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008 |
| DMEL | Derived Minimal Effect level |
| DNEL | Derived-No Effect Level |
| EC50 | Median effective concentration |
| IARC | International Agency for Research on Cancer |
| IATA | International Air Transport Association |
| IMDG | International Maritime Dangerous Goods |
| LC50 | Median lethal concentration |
| LD50 | Median lethal dose |
| LOAEL | Lowest Observed Adverse Effect Level |
| NOAEC | No-Observed Adverse Effect Concentration |

Witepsol® E 76

Safety Data Sheet

A safety data sheet is not required for this product in accordance with national legal requirements. This document has been created on a voluntary basis following the format of the safety data sheet.

| | |
|-------|---|
| NOAEL | No-Observed Adverse Effect Level |
| NOEC | No-Observed Effect Concentration |
| OECD | Organisation for Economic Co-operation and Development |
| PBT | Persistent Bioaccumulative Toxic |
| PNEC | Predicted No-Effect Concentration |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 |
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail |
| SDS | Safety Data Sheet |
| STP | Sewage treatment plant |
| TLM | Median Tolerance Limit |
| vPvB | Very Persistent and Very Bioaccumulative |

Data sources : ECHA (European Chemicals Agency). Information provided by the manufacturer.

Department issuing data : KFT Chemieservice GmbH
specification sheet: Im Leuschnerpark. 3 64347 Griesheim
Germany

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

Safety Data Sheet Service: +49 6155 8981-522

Contact person : Dr. Süleyman Cinar

KFT SDS EU 06

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.