



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

Printing date: 24.07.2017

Version: 4.04

Revision: 24.07.2017

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

· **1.1 Product identifier**

· Trade name: **SOFTISAN® 100**

· **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

· **Uses advised against** -

· **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 0111

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** The product is not classified according to the CLP regulation.

· **Information concerning particular hazards for human and environment:**

No hazards to be particularly mentioned. Please note the information of this Material Safety Data Sheet.

· **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

**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:**  
Wash with water and soap.  
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.  
In case of unintentional swallowing of larger quantities or if any symptoms occur seek medical treatment.
- **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.  
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:**  
Store container tightly sealed at a cool and dry place with sufficient ventilation.
- Information about storage in one common storage facility:**  
Store away from foodstuffs.  
Store away from feed.  
Refer to national regulations for storing hazardous chemicals.
- 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<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.
- Additional information:** The lists that were valid during the creation were used as basis.

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**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:**

Nitrile rubber, NBR

Butyl rubber, BR

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

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· <b>Self ignition temperature:</b>	Product is not self-igniting.
· <b>Explosive properties:</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** 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 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:**
- **Skin corrosion/irritation** Skin irritation test (rabbit): no irritation
- **Serious eye damage/irritation** Skin irritation test (rabbit): no irritation

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- **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.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction):**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity**

**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

Based on available data, the classification criteria are not met.

- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure**

**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

Based on available data, the classification criteria are not met.

- **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<sub>oc</sub>:**  
log K<sub>oc</sub> 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.  
Disposal according to instructions of local authorities

**· Uncleaned packagings:****· Recommendation:**

Disposal must be made according to official regulations.  
Packagings that cannot be cleaned are to be disposed of in the same manner as the product.  
If not officially regulated, non contaminated packagings can be used for recycling or treated like household garbage.

**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 Marpol and the IBC Code</b>	Not applicable
· <b>UN "Model Regulation":</b>	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

**· Further information:**

For this substance/mixture no safety data sheet needs to be generated according to Article 31(1) of Regulation (EC) No 1907/2006. The here presented safety data sheet may therefore not fulfil all requirements of Annex II of this regulation.

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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**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:**

Version/s 4. 03 is/are not available in this language.  
03.02.2016

• **Department issuing SDS:**

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• **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)

MAL-Code: Måleteknisk Arbejdshygiejnisk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark)

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

• **Sources:** Information provided by the manufacturer

• **\* Data compared to the previous version altered.**

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