

Glycerol mono-oleate (90)

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Revision date: 09/03/2015 :

Version: 1.1

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

1.1. Product identifier

Product form	: Mixture
Product name	: Glycerol mono-oleate (90)
Product code	: 900324
Product group	: Raw material
Other means of identification	: Mixture of monoacylglycerols, mainly mono-acylglycerols together with variable quantities of di- and triacylglycerols. It is defined by the nominal content of monoacylglycerols.

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

1.2.1. Relevant identified uses

Main use category	: Pharmaceutical
Use of the substance/mixture	: Exipient

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Duchefa FARMA BV
 A. Hofmanweg 71
 2031BH Haarlem - Nederland
 T +31(0)23-5319093 - F +31(0)23-5318027
info@duchefa.com - www.duchefa.com

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number
UNITED KINGDOM	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	0870 243 2241

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

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

Not classified

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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

Other hazards not contributing to the classification : None under normal conditions.

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

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 : Wash skin with mild soap and water.
First-aid measures after eye contact : Rinse with water. If eye irritation persists, take medical advice.
First-aid measures after ingestion : Rinse mouth. Drink plenty of water.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : All extinguishing agents can be used.

5.2. Special hazards arising from the substance or mixture

Explosion hazard : Product is not explosive.

5.3. Advice for firefighters

Precautionary measures fire : Exercise caution when fighting any chemical fire. Wear proper protective equipment.
Firefighting instructions : Prevent fire-fighting water from entering environment.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

No additional information available

6.3. Methods and material for containment and cleaning up

For containment : Dam up the liquid spill.

Methods for cleaning up : To clean the floor or objects contaminated by this product, use : Water.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

No additional information available

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Protect from light.

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

No additional information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Appearance : Viscous.

Colour : white. Slightly yellow.

Odour : No data available

Odour threshold : No data available

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pH	: 4 - 5
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 35 °C
Freezing point	: No data available
Boiling point	: 238 - 240 °C
Flash point	: 216 °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	: 0,942 g/cm ³
Solubility	: Insoluble in water. Soluble in ethanol. Soluble in chloroform.
Log Pow	: No data available
Viscosity, kinematic	: 100 m ² /s
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

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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

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LD50 oral rat	≥ 5000 mg/kg

Skin corrosion/irritation : Not classified
pH: 4 - 5

Serious eye damage/irritation : Not classified
pH: 4 - 5

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

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Viscosity, kinematic	100000000 mm ² /s

SECTION 12: Ecological information

12.1. Toxicity

Glycerol mono-oleate (90)	
LC50 fish 1	≥ 100 mg/l ISO 7346/2 (semistatic)

12.2. Persistence and degradability

No additional information available

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12.3. Bioaccumulative potential

Glycerol mono-oleate (90)	
Bioaccumulative potential	None.

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

Waste treatment methods : Avoid release to the environment.

SECTION 14: Transport information

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

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR) :

Proper Shipping Name (IMDG) :

Proper Shipping Name (IATA) :

Proper Shipping Name (ADN) :

Proper Shipping Name (RID) :

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) :

IMDG

Transport hazard class(es) (IMDG) :

IATA

Transport hazard class(es) (IATA) :

ADN

Transport hazard class(es) (ADN) :

RID

Transport hazard class(es) (RID) :

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14.4. Packing group

Packing group (ADR)	:	
Packing group (IMDG)	:	
Packing group (IATA)	:	
Packing group (ADN)	:	
Packing group (RID)	:	

14.5. Environmental hazards

Dangerous for the environment	:	No
Marine pollutant	:	No
Other information	:	No supplementary information available

14.6. Special precautions for user

14.6.1. Overland transport

14.6.2. Transport by sea

14.6.3. Air transport

14.6.4. Inland waterway transport

Carriage prohibited (ADN)	:	No
Not subject to ADN	:	No

14.6.5. Rail transport

Carriage prohibited (RID)	:	No
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14.7. Transport in bulk according to Annex II of MARPOL 73/78 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 substances with Annex XVII restrictions

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier

SECTION 16: Other information

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Data sources

: 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. Handbook Of Pharmaceutical Excipients. Supplier. EP.

SDS EU (REACH Annex II) Duchefa

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