

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

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Version: 00

# MACROGOL-7-GLYCEROL COCOATE

# SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1 PRODUCT IDENTIFIER

Product name: EN: Macrogol-7-glycerol cocoate

LAT: Macrogolglyceroli cocoates

NL: Macrogol-7-glycerol cocoaat

FR: Macrogol-7-glycérol (cocoate de)

DE: Macrogol-7-glycerolcocoat

N° CAS: 68201-46-7 N° EC: 614-376-4

### 1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE/MIXTURE AND USES ADVISED AGAINST

Identified uses: Active Pharmaceutical Ingredient or Excipient.

### 1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Company: Magis-Pharma NV

Neerlandweg 24 2610 Wilrijk Belgium

Telephone: (+32) (0)3 457 11 76
Email: info@magis-pharma.be
Web page: www.magis-pharma.be

## 1.4 EMERGENCY TELEPHONE NUMBER

Public utility foundation: Belgisch Antigifcentrum Centre Antipoisons Belge

Telephone: (+32) (0)70 245 245 (Service 24/7)

Web page: www.antigifcentrum.be www.centreantipoisons.be

## **SECTION 2: HAZARDS IDENTIFICATION**

## 2.1 CLASSIFICATION OF THE SUBSTANCE/MIXTURE

Classification according to (EC) n° 1272/2008

Not applicable.

## **2.2 LABEL ELEMENTS**

## Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s):

Not applicable.

Hazard statements:

Not applicable.

Precautionary statements:

Additional applicable label

Not applicable.

elements:

# 2.3 OTHER HAZARDS

This substance / mixture contains no components that can be considered as persistent, bioaccumulative and toxic (PBT) or as very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

May cause irritation to eyes and skin. May cause respiratory tract irritation. May cause mucous membrane irritation.



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# SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### **3.1 SUBSTANCES**

Product name: Macrogol-7-glycerol cocoate

IUPAC name: Not available.

Synonyms: PEG-7 glyceryl cocoate.

N° CAS:Not applicable.N° EC:Not applicable.Molecular Formula:Not applicable.Content:Not available.

### **3.2 MIXTURES**

Not applicable.

### **SECTION 4: FIRST AID MEASURES**

## **4.1 DESCRIPTION OF FIRST AID MEASURES**

After inhalation: If symptoms persist, seek medical advice.

After skin contact: Take off contaminated clothing and shoes immediately. Wash off with soap and

plenty of water.

After eye contact: Immediately flush eyes with plenty of water. Consult a specialist if irritation persists.

After ingestion: Seek medical attention. Consult a doctor if symptoms persist.

# 4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

None known.

# 4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

None known.

## **SECTION 5: FIREFIGHTING MEASURES**

# **5.1 EXTINGUISHING MEDIA**

Suitable extinguishing media: Use extinguishing measures that are appropriate to local

circumstances and the environment.

Use water spray, alcohol-resistant foam, dry powder, or carbon

dioxide.

Unsuitable extinguishing media: Strong water jet.

# 5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE/MIXTURE

Do not use a fixed stream of water as it may burst and spread fire.

## **5.3 ADVICE FOR FIREFIGHTERS**

Surrounding fires: Standard procedure for chemical fires.

Protection against fire: In the event of fire, wear self-contained breathing apparatus.

Hazardous combustion products: Not available.



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## **SECTION 6: ACCIDENTAL RELEASE MEASURES**

## **6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES**

#### FOR NON-EMERGENCY PERSONNEL

Use personal protective equipment.

Ensure adequate ventilation.

### FOR EMERGENCY RESPONDERS

Not available.

### **6.2 ENVIRONMENTAL PRECAUTIONS**

Prevent product from entering drains.

## 6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Sweep up and brag.

### **6.4 REFERENCE TO OTHER SECTIONS**

Not available.

### **SECTION 7: HANDLING AND STORAGE**

## 7.1 PRECAUTIONS FOR SAFE HANDLING

Precautions for safe handling: No special instructions for use required.

Personal protection: Not available.

Technical protective measures: Normal measures for preventive fire protection.

Handling: Use in accordance with current rules and practices regarding

industrial hygiene and safety.

## 7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Storage: Store in original container.

Conditions for safe storage, including any

incompatibilities:

Keep container tightly closed in a dry and well-ventilated place. No

special restrictions for storage together with other substances.

Storage – away from: Not available.

# 7.3 SPECIFIC END USE(S)

Active Pharmaceutical Ingredient or Excipient

## **SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

## **8.1 CONTROL PARAMETERS**

The product contains no components for which MAC values are specified.

# **8.2 EXPOSURE CONTROLS**

## APPROPRIATE ENGINEERING CONTROL

Not available.

## **INDIVIDUAL PROTECTION MEASURES**

Eye/face protection: Safety glasses.

Skin protection: Impenetrable clothing.

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Hand protection: Wear gloves in case of persistent or repeated contact. Respiratory protection: No personal respiratory protection required for normal use.

Thermal hazards: Not available.

### **ENVIRONMENTAL EXPOSURE CONTROL**

Not available.

## **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

### 9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear, yellowish, oily liquid.

Odour: Not available. Odour threshold: Not available. :Ha Not available. Not available. Melting/freezing point: Initial boiling point: Not available. Boiling range: Not available.

>100°C Flash point:

Evaporation rate: Not available. Flammability (solid/gas): Not available. Not available. Upper/lower flammability or

explosive limits:

Vapour pressure: Not available. Vapour density: Not available. Not available. Relative density:

Solubility: 100 g/l

Soluble in ethanol (96 per cent) and practically insoluble in light petroleum (bp: 50-

70°C) for macrogol 7 glycerol cocoate and macrogol 23 glycerol cocoate.

Solubility in water: 100 g/l

Soluble in water

Partition coefficient

Not available.

(n-octanol/water):

Not available.

Auto-ignition temperature: Decomposition temperature: Not available. Viscosity: Not available. Explosive properties: Not available. Oxidising properties: Not available.

## 9.2 OTHER INFORMATION

Not available.



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# **SECTION 10: STABILITY AND REACTIVITY**

**10.1 REACTIVITY** 

Not available.

**10.2 CHEMICAL STABILITY** 

Not available.

**10.3 POSSIBILITY OF HAZARDOUS REACTIONS** 

Not available.

**10.4 CONDITIONS TO AVOID** 

Not available.

**10.5 INCOMPATIBLE MATERIALS** 

Strong oxidizing agents.

**10.6 HAZARDOUS DECOMPOSITION PRODUCTS** 

Not available.

## **SECTION 11: TOXICOLOGICAL INFORMATION**

## 11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity: LD<sub>50</sub> rat: >19.900 mg/kg

Skin corrosion/irritation: Epicutane test on test persons showed no irritating properties.

Method: in vitro study Remarks: slight skin irritation

Serious eye damage/irritation: Based on available data, the classification criteria are not met.

Respiratory/skin sensitisation: Epicutaneous tests on test persons have shown no sensitizing properties.

Germ cell mutagenicity: Not available.

Carcinogenicity: Not available.

Reproductive toxicity: Not available.

Summary of evaluation of the Not available.

CMR properties:

STOT-single exposure: Not available.

STOT-repeated exposure: Not available.

Aspiration Hazard: Not available.

Other: Not available.

# 11.2 ADDITIONAL INFORMATION ON POTENTIAL ADVERSE HUMAN HEALTH EFFECTS AND SYMPTOMS

Eye contact:

Skin contact:

Inhalation:

Ingestion:

Aspiration:

Not available.

Not available.

Not available.

Not available.



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### **SECTION 12: ECOLOGICAL INFORMATION**

### **12.1 TOXICITY**

Not available.

### 12.2 PERSISTENCE AND DEGRADABILITY

Expected to be biodegradable.

## 12.3 BIOACCUMULATIVE POTENTIAL

Not available.

### **12.4 MOBILITY IN SOIL**

Not available.

### 12.5 RESULTS OF PBT AND VPVB ASSESSMENT

This substance / mixture contains no components that can be considered as persistent, bioaccumulative and toxic (PBT) or as very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 OTHER ADVERSE EFFECTS

Not available.

### **SECTION 13: DISPOSAL CONSIDERATIONS**

## **13.1 WASTE TREATMENT METHODS**

Product: Dispose of in accordance with local regulations.

Contaminated packaging: remove remaining residue.

Empty containers must be taken to an approved waste processing center for reuse or disposal.

## **SECTION 14: TRANSPORT INFORMATION**

## Transport information according to ADR/RID/IMDG/ICAO/IATA

### **14.1 UN NUMBER**

ADR/ RID(Land),IMDG(Sea), Not available.

IATA/ICAO (Air):

## **14.2 UN PROPER SHIPPING NAME**

ADR/ RID(Land),IMDG(Sea), Not available.

IATA/ICAO (Air):

# 14.3 TRANSPORT HAZARD CLASS(ES)

ADR/ RID(Land),IMDG(Sea), Not available.

IATA/ICAO (Air):

# **14.4 PACKING GROUP**

ADR/ RID(Land),IMDG(Sea), Not available.

IATA/ICAO (Air):

## **14.5 ENVIRONMENTAL HAZARDS**

ADR/ RID(Land),IMDG(Sea), Not available.

IATA/ICAO (Air):

### **14.6 SPECIAL PRECAUTIONS FOR USER**

Not available.

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## 14.7 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL AND THE IBC CODE

Not available.

### 14.8 ADDITIONAL TRANSPORT INFORMATION

Not available.

## **SECTION 15: REGULATORY INFORMATION**

## 15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE/MIXTURE

Hazard symbol: Not available.
Risk phrases: Not available.
Safety phrases: Not available.

## **15.2 CHEMICAL SAFETY ASSESSMENT**

Not available.

### **SECTION 16: OTHER INFORMATION**

### **16.1 CHANGES SINCE THE PREVIOUS VERSION**

Not applicable.

## **16.2 ABBREVIATIONS AND ACRONYMS USED**

ADR: European Agreement concerning the International Carriage of Dangerous Goods by

Road

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

EC (number): European Community (number)

IATA: International Air Transport Association
ICAO: International Civil Aviation Organization

IMDG: International Maritime Code for Dangerous Goods
 IUPAC: International Union of Pure and Applied Chemistry
 PBT: Persistent, Bioaccumulative and Toxic substance

RID: Regulations Concerning the International Transport of Dangerous Goods by Rail

STOT: Specific Target Organ Toxicity
UN (number): United Nations (number)

vPvB: very Persistent and very Bioaccumalative

## 16.3 KEY LITERATURE REFERENCES/SOURCES FOR DATA

European Chemicals Agency.

https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/

## **16.4 METHOD OF CLASSIFICATION IN CASE OF MIXTURE**

Not applicable.

# 16.5 RELEVANT HAZARD STATEMENTS AND/OR PRECAUTIONARY STATEMENTS

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

# **16.6 TRAINING ADVISEMENT**

Not available

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# 16.7 NOTICE FOR USER(S)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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### **16.8 DEPARTMENT ISSUING MSDS**

Magis-Pharma NV info@magis-pharma.be

