

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 1/9

Publication: 08/11/2022

Revision: XX/XX/XXXX

Version: 00



## POLYSORBATUM

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

#### 1.1 Product identifier

Product name:	Polysorbate 80 Polysorbatum 80 Polysorbaat 80 Polysorbate 80 Polysorbat 80
N° CAS:	9005-65-6
N° EC:	500-019-9

#### 1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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#### 1.3 Details of the supplier of the safety data sheet

Company:	FRAVER NV Keizershoek 336 2550 Kontich 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 a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

#### 2.2 Label elements

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

Hazard pictogram(s):	Not applicable.
Signal word(s):	Not applicable.
Hazard statements:	Not applicable.
Precautionary statements:	Not applicable.
Additional applicable label elements:	Not applicable.

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 2/9

Publication: 08/11/2022

Revision: XX/XX/XXXX

Version: 00



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## POLYSORBATUM

### 2.3 Other hazards

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

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Polysorbate 80
IUPAC name:	2-[2-[3,5-bis(2-hydroxyethoxy)oxolan-2-yl]-2-(2-hydroxyethoxy)ethoxy]ethyl (E)-octadec-9-enoate
Synonyms:	Polyethylene glycol sorbitan mono-oleate Tween 80
N° CAS:	9005-65-6
N° EC:	500-019-9
Content:	Mixture of partial esters of fatty acids, mainly <i>Oleic acid (0799)</i> , with sorbitol and its anhydrides ethoxylated with approximately 20 moles of ethylene oxide for each mole of sorbitol and sorbitol anhydrides.

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

After inhalation:	If breathed in, move person into fresh air. If symptoms persist, call a physician.
After skin contact:	In case of contact, immediately flush skin with soap and plenty of water. If symptoms persist, call a physician.
After eye contact:	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
After ingestion:	If large quantities of this material are swallowed, call a physician immediately.

### 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 surrounding environment. Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Unsuitable extinguishing media:	High volume water jet.

### 5.2 Special hazards arising from the substance/mixture

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 3/9

Publication: 08/11/2022

Revision: XX/XX/XXXX

Version: 00



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## POLYSORBATUM

Specific hazards during firefighting: Do not use a solid water stream as it may scatter and spread fire. Do not allow run-off from fire fighting to enter drains or water courses.

### 5.3 Advice for firefighters

Surrounding fires:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Protection against fire:	In the event of fire, wear self-contained breathing apparatus.
Hazardous combustion products:	Not available.

## 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

Use personal protective equipment. Ensure adequate ventilation.

### 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.

Sweep up and shovel into suitable containers for disposal.

### 6.4 Reference to other sections

Not available.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:	Handle in accordance with good industrial hygiene and safety practice. Normal measures for preventive fire protection.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Handle in accordance with good industrial hygiene and safety practice.

### 7.2 Conditions for safe storage, including any incompatibilities

Storage:	In an airtight container. Store in original container. Stable under recommended storage conditions.
Conditions for safe storage, including any incompatibilities:	Keep container tightly closed in a dry and well-ventilated place. No special restrictions on storage with other products.
Storage – away from:	Protected from light.

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 4/9

Publication: 08/11/2022

Revision: XX/XX/XXXX

Version: 00



## POLYSORBATUM

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Contains no substances with occupational exposure limit values.

### 8.2 Exposure controls

#### Appropriate engineering control

Not available.

#### Individual protection measures

Eye/face protection: Safety glasses.

Skin protection: Impervious clothing.

Hand protection: For prolonged or repeated contact use protective gloves.

Respiratory protection: No personal respiratory protective equipment normally required.

Thermal hazards: Not determined.

#### Environmental exposure control

Not available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance: Oily, colourless or brownish-yellow, clear or slightly opalescent liquid.

Odour: Not available.

Odour threshold: Not available.

pH: Neutral.

Melting/freezing point: Not available.

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: > 100 °C

Evaporation rate: Not available.

Flammability (solid/gas): Not available.

Upper/lower flammability or explosive limits: Not available.

Vapour pressure: Not available.

Vapour density: Not available.

Relative density: About 1.10

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 5/9

Publication: 08/11/2022

Revision: XX/XX/XXXX

Version: 00



## POLYSORBATUM

Solubility:	Dispersible in anhydrous ethanol, in ethyl acetate and in methanol, practically insoluble in fatty oils and in liquid paraffin.
Solubility in water:	Dispersible in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Kinematic: 300 - 500 mm <sup>2</sup> /s (25 °C)
Explosive properties:	Not available.
Oxidising properties:	Not available.

### 9.2 Other information

Density: 1.06 – 1.09 g/cm<sup>3</sup> (25 °C)

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Not available.

### 10.2 Chemical stability

Not available.

### 10.3 Possibility of hazardous reactions

Stable under recommended storage conditions.

### 10.4 Conditions to avoid

None known.

### 10.5 Incompatible materials

Strong oxidising agents.

### 10.6 Hazardous decomposition products

Not available.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Oral LD <sub>50</sub> (rat): 20 000 mg/kg Test substance: 100 % Remarks: Low acute toxicity.
Skin corrosion/irritation:	Species: Rabbit Exposure time: 72 h Method: Draize Test Result: Not irritating Test substance: 100 %

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 6/9

Publication: 08/11/2022

Revision: XX/XX/XXXX

Version: 00



## POLYSORBATUM

Serious eye damage/irritation:	Species: Rabbit Exposure time: 168 h Method: Draize Test Result: Not irritating Test substance: 100 %
Respiratory/skin sensitisation:	Species: Humans Result: Patch test on human volunteers did not demonstrate sensitisation properties. Test substance: 100 %
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
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:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

#### Toxicity to fish

LC<sub>50</sub> (*Oncorhynchus mykiss* (rainbow trout)): 471 mg/l

Exposure time: 96 h

Test type: static test

#### Toxicity to daphnia and other aquatic invertebrates

LC<sub>50</sub> (*Mysidopsis bahia*): 165 mg/l

Exposure time: 96 h

Test Type: static test

#### Toxicity to microorganisms

IC<sub>0</sub> (*Pseudomonas putida*): > 10 000 mg/l

### 12.2 Persistence and degradability

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 7/9

Publication: 08/11/2022

Revision: XX/XX/XXXX

Version: 00



## POLYSORBATUM

Test Type: static test  
Biodegradation: 100 %  
Exposure time: 100 d

Test Type: (OECD 301B)  
Result: Biodegradable  
Biodegradation: 64 %  
Exposure time: 29 d  
Method: OECD Test Guideline 301B  
GLP: yes

### 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 considered to be either persistent, bioaccumulative and toxic (PBT), or 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: Empty remaining contents. Empty containers should be taken to an approved waste handling site for recycling or disposal.

## SECTION 14: TRANSPORT INFORMATION

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

#### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : Not classified.

#### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : Not classified.

#### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : Not classified.

#### 14.4 Packing group

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 8/9

Publication: 08/11/2022

Revision: XX/XX/XXXX

Version: 00



## POLYSORBATUM

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

### 14.6 Special precautions for user

Not classified as dangerous in the meaning of transport regulations.

### 14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not applicable for product as supplied.

### 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 applicable.

Risk phrases: Not applicable.

Safety phrases: Not applicable.

### 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)



# Material Safety Data Sheet

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

## POLYSORBATUM

EN

FORM-06-14-01 (V00)

Page 9/9

Publication: 08/11/2022

Revision: XX/XX/XXXX

Version: 00



vPvB: very Persistent and very Bioaccumulative

### 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

Classification based on the main component.

### 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

### 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

Quality Department

FRAVER NV

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