

Macrogol stearyl ether (20)

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Date of issue: 01/06/2015 Revision date:

Version: 1.0

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

1.1. Product identifier

Product form : Substance
Substance name : Macrogol stearyl ether (20)
Chemical name : Alkyl polyglycol ether C16-C18
CAS No : 68439-49-6
Product code : 642681
Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical industry
Industrial/Professional use spec : For professional use only
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

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2031BH Haarlem - Nederland
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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]

Acute Tox. 4 (Oral) H302
Eye Dam. 1 H318

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Full text of H-phrases: see section 16

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

Xn; R22

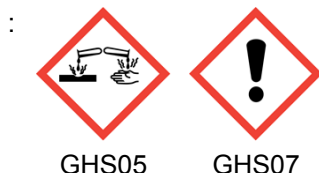
Xi; R41

Full text of R-phrases: see section 16

2.2. Label elements

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

Hazard pictograms (CLP)



GHS05

GHS07

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H302 - Harmful if swallowed
H318 - Causes serious eye damage

Precautionary statements (CLP)

: P280 - Wear protective gloves/protective clothing/eye protection/face protection
P301+P312 - IF SWALLOWED: call a POISON CENTER or doctor/physician if you feel unwell
P330 - Rinse mouth
P305 - IF IN EYES:
P351 - Rinse cautiously with water for several minutes
P310 - Immediately call a POISON CENTER or doctor/physician

2.3. Other hazards

Other hazards not contributing to the classification : Dust may form explosive mixture in air.

SECTION 3: Composition/information on ingredients

3.1. Substance

Name : Macrogol stearyl ether (20)

CAS No : 68439-49-6

Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Macrogol stearyl ether (20)	(CAS No) 68439-49-6	100	Xn; R22 Xi; R41	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318

Full text of R- and H-phrases: see section 16

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3.2. Mixture

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after skin contact : Wash with plenty of soap and water.

First-aid measures after eye contact : Immediately flush eyes thoroughly with water for at least 15 minutes. Seek medical attention immediately.

First-aid measures after ingestion : Rinse mouth. Drink two glasses 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 : dry chemical powder, alcohol-resistant foam, carbon dioxide (CO₂). Water spray.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Carbon oxides (CO, CO₂).

5.3. Advice for firefighters

Protection during firefighting : Wear self-contained breathing apparatus, rubber boots and thick rubber gloves.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with skin and eyes.

6.1.1. For non-emergency personnel

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up, shovel or vacuum.

6.4. Reference to other sections

Reference to other sections (8, 13).

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : No open flames. No smoking.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed.

Storage temperature : 15 - 25 °C

Packaging materials : PE.

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

Appropriate engineering controls : Handle in accordance with good industrial hygiene and safety practice.

Hand protection : Wear gloves to EN374 to protect against skin effects from powders. Avoid carrying out operation for more than 15 minutes. The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection : Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection : Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection : Dustmask with filtertype P1

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid

Appearance : Waxy. Flakes. Tablets.

Colour : white to slightly yellow.

Odour : No data available

Odour threshold : No data available

pH : 6 - 7,5

Relative evaporation rate
(butylacetate=1) : No data available

Melting point : 39 - 41 °C

Freezing point : No data available

Boiling point : No data available

Flash point : 249 - 251 °C

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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	: $\approx 1,02$ 60 degrees
Solubility	: Completely miscibility with water.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: Potential dust explosion hazard from airborne release.
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

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

Strong acids. Bases.

10.4. Conditions to avoid

Avoid raising dust/heat. Use special care to avoid static electric charges.

10.5. Incompatible materials

Oxidizing agent. Strong acids. Strong bases.

10.6. Hazardous decomposition products

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

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Oral: Harmful if swallowed.

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LD50 oral rat	300 - 2000 mg/kg
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Skin corrosion/irritation	: Not classified pH: 6 - 7,5
Serious eye damage/irritation	: Causes serious eye damage. pH: 6 - 7,5
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

SECTION 12: Ecological information

12.1. Toxicity

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LC50 fish 1	1 - 10 mg/l
ErC50 (algae)	<= mg/l

12.2. Persistence and degradability

Macrogol stearyl ether (20) (68439-49-6)

Persistence and degradability	Biodegradable.
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12.3. Bioaccumulative potential

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Bioaccumulative potential	unlikely.
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

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12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to official regulations.
Waste disposal recommendations : Dispose of contaminated material at an authorized site.

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) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

14.5. Environmental hazards

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

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14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Inland waterway transport

Carriage prohibited (ADN) : No

Not subject to ADN : No

- Rail transport

Carriage prohibited (RID) : No

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

No REACH Annex XVII restrictions

Macrogol stearyl ether (20) is not on the REACH Candidate List

Macrogol stearyl ether (20) is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

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.

Full text of R-, H- and EUH-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
H302	Harmful if swallowed
H318	Causes serious eye damage
R22	Harmful if swallowed
R41	Risk of serious damage to eyes
Xi	Irritant
Xn	Harmful

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