

POLYSORBATE 80

Product Safety Information Sheet

A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on a voluntary basis

Reference number: POLYSORBATE 80

Issue date: 11/15/2021 Revision date: 2/21/2022 Supersedes version of: 11/15/2021 Version: 8.0

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

1.1. Product identifier

Product form	: Substance
Substance name	: POLYSORBATE 80
CAS-No.	: 9005-65-6
REACH registration No	: Exempte polymère
Product code	: POLYSORBATE 80

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Emulsifiant

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of product safety information sheet

INTERCHIMIE
ZAC du Parc 13 rue Louis Blériot
FR- 77290 COMPANS
T T: +33 (0)1 64 77 76 27
qualite@interchimie.fr - www.interchimie.fr

1.4. Emergency telephone number

No additional information available

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

No labelling applicable

2.3. Other hazards

Not applicable.

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substances

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Name	Product identifier	%
Sorbitan monooleate, ethoxylated	CAS-No.: 9005-65-6 EC-No.: 500-019-9 REACH-no: EXEMPTED POLYMERE	≥ 100

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: This product is not considered to be hazardous.
First-aid measures after inhalation	: If you feel unwell, seek medical advice. Allow affected person to breathe fresh air.
First-aid measures after skin contact	: Wash with soapy water.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes.
First-aid measures after ingestion	: Rinse mouth out with water. Do not induce vomiting. Get medical advice/attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects	: Not expected to present a significant hazard under anticipated conditions of normal use.
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4.3. Indication of any immediate medical attention and special treatment needed

May result in aspiration into the lungs.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Making extinguishing agents environment-friendly.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released. Carbon dioxide. Carbon monoxide.
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5.3. Advice for firefighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment.
Other information	: Prevent fire fighting water from entering the environment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Spill area may be slippery. Evacuate area.
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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

Avoid release to the environment. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Take up liquid spill into absorbent material.
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6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of solid materials or residues refer to section 13 : "Disposal considerations".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : This product is not considered to be hazardous. Do not eat, drink or smoke when using this product.
Hygiene measures : Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Information on mixed storage : Combustible liquid.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No additional information available

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

Safety glasses. EN 166

8.2.2.2. Skin protection

Hand protection:

Nitrile rubber gloves

Other skin protection

Materials for protective clothing:

Protective clothing

8.2.2.3. Respiratory protection

Respiratory protection:

No respiratory protection needed under normal use conditions

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8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Other information:

Do not eat, drink or smoke when using this product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: pale.
Odour	: characteristic.
Odour threshold	: No data available
pH	: No data available
pH solution	: 6 – 7.5 (10g/l - 20°C)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: < 0 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: ≈ 276 °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	: 1.08 g/cm ³ (25°C)
Solubility	: Miscible.
Partition coefficient n-octanol/water (Log Pow)	: emulsifiant
Viscosity, kinematic	: No data available
Viscosity, dynamic	: 450 mPa·s (40°C)
Explosive properties	: No dangerous reactions known.
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

The product is stable at normal handling and storage conditions.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Stable under normal conditions of use.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Carbon monoxide. Carbon dioxide. fume.

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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

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LD50 oral rat	> 2000 mg/kg (OECD 401) biblio
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Catégorie de pollution des eaux 1 (Classification propre) : Peu polluant.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

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LC50 - Fish [1]	10 – 100 mg/l (CESIO 10/2015)
EC50 - Crustacea [1]	10 – 100 mg/l (CESIO 10/2015)
EC50 72h - Algae [1]	10 – 100 mg/l (CESIO 10/2015)

12.2. Persistence and degradability

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Persistence and degradability	Not readily biodegradable.
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12.3. Bioaccumulative potential

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Partition coefficient n-octanol/water (Log Pow)	emulsifiant
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

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Not applicable.

12.6. Other adverse effects

No additional information available

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to official regulations.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Transport in bulk according to Annex II of Marpol 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

POLYSORBATE 80 is not on the REACH Candidate List

POLYSORBATE 80 is not on the REACH Annex XIV List

POLYSORBATE 80 is not subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

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POLYSORBATE 80 is not subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

POLYSORBATE 80 is not subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

Contains no substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

15.1.2. National regulations

Germany

Water hazard class (WGK) : WGK 1, Slightly hazardous to water (Classification according to VwVwS, Annex 3; ID No. 3699)

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed

SZW-lijst van mutagene stoffen : The substance is not listed

SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed

SZW-lijst van reprotoxische stoffen – : The substance is not listed

Vruchtbaarheid

SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

Denmark

Classification remarks : Emergency management guidelines for the storage of flammable liquids must be followed

Switzerland

Storage class (LK) : LK 10/12 - Liquids

15.2. Chemical safety assessment

This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

SECTION 16: Other information

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Indication of changes			
Section	Changed item	Change	Comments
	Supersedes version of	Modified	
	Revision date	Modified	
	Issue date	Modified	
1.1	CAS-No.	Modified	

Data sources : This MSDS has been established with data of MSDS coming from upstream suppliers.

Safety Data Sheet (SDS), EU