

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 20 Issue date: 7/21/2021 Revision date: 2/20/2024 Supersedes version of: 7/21/2021 Version: 3.1

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

1.1. Product identifier

Product form
Substance name
CAS-No.
REACH registration No.
Product code

Substance
POLYSORBATE 20
9005-64-5
Exempte polymère
POLYSORBATE 20

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

1.2.1. Relevant identified uses

: Emulsifiant

Use of the substance/mixture 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 gualite@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

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII Not applicable.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII Contains no PBT and/or vPvB substances \geq 0.1% assessed in accordance with REACH Annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substances

Name CAS-No. : POLYSORBATE 20 : 9005-64-5

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Name	Product identifier	%
Sorbitan monolaurate, ethoxylated	CAS-No.: 9005-64-5 EC-No.: 500-018-3 EC Index-No.: Exp REACH-no: EXEMPTE POLYMERE	≥ 100

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

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4.1. Description of first aid measures				
First-aid measures general	: This product is not considered to be hazardous. When in doubt or if symptoms are observed, get medical advice.			
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				

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Symptoms/effects
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: Not expected to present a significant hazard under anticipated conditions of normal use.

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 Unsuitable extinguishing media	Making extinguishing agents environment-friendly.Do not use a heavy water stream.
5.2. Special hazards arising from the subst	tance or mixture
Hazardous decomposition products in case of fire	: Toxic fumes may be released. Carbon dioxide. Carbon monoxide.
5.3. Advice for firefighters	
Protection during firefighting Other information	Do not attempt to take action without suitable protective equipment.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.

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.

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6.3. Methods and material for containment and cleaning up

Methods for cleaning up

: Take up liquid spill into absorbent material.

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 stora	age
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, in	cluding any incompatibilities
Storage temperature Information on mixed storage	: 5 − 40 °C : 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

POLYSORBATE 20 (9005-64-5)		
PNEC (Water)		
PNEC aqua (freshwater)	0.2 mg/l	
PNEC aqua (marine water)	0.02 mg/l	
PNEC (Sediment)		
PNEC sediment (freshwater)	1.141 mg/kg dwt	
PNEC sediment (marine water)	1000 mg/kg dwt	

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

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8.2.2.1. Eye and face protection

Eye protection:

Safety glasses. ISO 16321-1

8.2.2.2. Skin protection

Hand protection:

Nitrile rubber gloves

Hand protection					
Туре	Material	Permeation	Thickness (mm)	Penetration	Standard
	Nitrile rubber (NBR)	4 (> 120 minutes)	> 0.5mm		EN ISO 374

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

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	: light yellow.		
Odour	: characteristic.		
Odour threshold	: Not available		
Melting point	: <0°C		
Freezing point	: Not available		
Boiling point	: Not available		
Flammability	: Not available		
Explosive properties	: No dangerous reactions known.		
Lower explosion limit	: Not available		
Upper explosion limit	: Not available		
Flash point	: 330 °C		
Auto-ignition temperature	: Not available		
Decomposition temperature	: 300 °C		
рН	: Not available		
pH solution	: 5 g/l =5.0-8.0		
Viscosity, kinematic	: Not available		
Viscosity, dynamic	: 400 cP (20°C)		
Solubility	: Not available		
Partition coefficient n-octanol/water (Log Kow)	: Not available		
Vapour pressure	: Not available		
Vapour pressure at 50°C	: < 300kPa		
Density	: Not available		
Relative density	: 1.05 – 1.1 g/cm3 (60°C)		
Relative vapour density at 20°C	: Not available		
Particle characteristics	: Not applicable		

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9.2. Other information

- 9.2.1. Information with regard to physical hazard classes
- No additional information available

9.2.2. Other safety characteristics

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.

SECTION 11: Toxicological information 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008 Acute toxicity (oral) Not classified Acute toxicity (dermal) Not classified Acute toxicity (inhalation) Not classified : **POLYSORBATE 20 (9005-64-5)** LD50 oral rat 40554 mg/kg LD50 dermal > 2000 mg/kg LC50 Inhalation - Rat > 20 mg/l 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 5 Aspiration hazard : Not classified 11.2. Information on other hazards

No additional information available

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SECTION 12: Ecological information	
12.1. Toxicity	
Hazardous to the aquatic environment, short–term : (acute)	Catégorie de pollution des eaux 1 (Classification propre) : Peu polluant. Not classified Not classified
12.2. Persistence and degradability	
POLYSORBATE 20 (9005-64-5)	
Persistence and degradability	Not readily biodegradable.
Sorbitan monolaurate, ethoxylated (9005-64-	5)
Persistence and degradability	Rapidly degradable
12.3. Bioaccumulative potential	
POLYSORBATE 20 (9005-64-5)	
Bioaccumulative potential	Bioaccumulation unlikely.
12.4. Mobility in soil	
No additional information available	
12.5. Results of PBT and vPvB assessment	
POLYSORBATE 20 (9005-64-5)	
This substance/mixture does not meet the PBT criteria	a of REACH regulation, annex XIII
Not applicable.	
This substance/mixture does not meet the vPvB criter	ia of REACH regulation, annex XIII
12.6. Endocrine disrupting properties	
Adverse effects on the environment caused by endocrine disrupting properties	Not reported evidence concerning this effect.
12.7. Other adverse effects	
No additional information available	
SECTION 13: Disposal considerations	

13.1. Waste treatment methods

Regional waste regulation

: 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 or ID number						
Not regulated for transport						

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ADR	IMDG	ΙΑΤΑ	ADN	RID
14.2. UN proper shippin	g 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

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

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

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

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Dual-Use Regulation (428/2009)

Contains no substance subject to the COUNCIL REGULATION (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 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. 3692).
Hazardous Incident Ordinance (12. BImSchV)	:	Is not subject to 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 – Vruchtbaarheid	:	The substance is not listed
SZW-lijst van reprotoxische stoffen – Ontwikkeling	:	The substance is not listed

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			
4.1	First-aid measures general	Modified			
7.2	Storage temperature	Added			
8.1	PNEC sediment (marine water)	Added			
8.1	PNEC sediment (freshwater)	Added			
8.1	PNEC aqua (marine water)	Added			
8.1	PNEC aqua (freshwater)	Added			
9.1	Vapour pressure at 50°C	Added			
9.1	Decomposition temperature	Added			
9.1	Colour	Added			
9.1	Viscosity, dynamic	Modified			
9.1	Relative density	Modified			
9.1	pH solution	Modified			
11.1	LD50 dermal	Added			

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Indication of changes				
Section	Changed item	Change	Comments	
11.1	LC50 Inhalation - Rat	Added		
11.1	LD50 oral rat	Modified		
12.6	Adverse effects on the environment caused by endocrine disrupting properties	Added		

Data sources

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

Safety Data Sheet (SDS), EU