

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version 8.6 Revision Date 05.07.2022 Print Date 06.08.2024 GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

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

1.1	Product identifiers Product name	:	Polysorbate 20 high purity E	
	Product Number Catalogue No. Brand REACH No.	:	1.37172137172MilliporeA registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.	
	CAS-No.	:	9005-64-5	
1.2	Relevant identified uses of the substance or mixture and uses advised against			
	Identified uses	:	Pharmaceutical production and analysis	
1.3	B Details of the supplier of the safety data sheet			
	Company	:	Sigma-Aldrich Chemie GmbH Eschenstrasse 5 D-82024 TAUFKIRCHEN	
	Telephone Fax E-mail address	:	+49 (0)89 6513-1130 +49 (0)89 6513-1161 technischerservice@merckgroup.com	
1.4	Emergency telephone			
	Emergency Phone #	:	0800 181 7059 (CHEMTREC Deutschland) +49 (0)696 43508409 (CHEMTREC weltweit)	

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

2.2 Label elements

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

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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

Formula	:	C58H114O26
Molecular weight	:	1.228 g/mol
CAS-No.	:	9005-64-5
EC-No.	:	500-018-3

No components need to be disclosed according to the applicable regulations.

SECTION 4: First aid measures

4.1 Description of first-aid measures

If inhaled

After inhalation: fresh air.

In case of skin contact

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower.

In case of eye contact

After eye contact: rinse out with plenty of water. Remove contact lenses.

If swallowed

After swallowing: make victim drink water (two glasses at most). Consult doctor if feeling unwell.

4.2 Most important symptoms and effects, both acute and delayed The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water Foam Carbon dioxide (CO2) Dry powder

Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

Carbon oxides Combustible. Vapors are heavier than air and may spread along floors. Forms explosive mixtures with air on intense heating. Development of hazardous combustion gases or vapours possible in the event of fire.

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5.3 Advice for firefighters

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

5.4 Further information

Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Advice for non-emergency personnel: Do not breathe vapors, aerosols. Evacuate the danger area, observe emergency procedures, consult an expert. For personal protection see section 8.
- **6.2 Environmental precautions** Do not let product enter drains.
- **6.3 Methods and materials for containment and cleaning up** Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material (e.g. Chemizorb®). Dispose of properly. Clean up affected area.
- **6.4** Reference to other sections For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions Tightly closed.

Recommended storage temperature see product label.

Storage class Storage class (TRGS 510): 10: Combustible liquids

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with workplace control parameters

8.2 Exposure controls

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

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Skin protection

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de). Full contact Material: Nitrile rubber Minimum layer thickness: 0,4 mm Break through time: 480 min Material tested:Camatril® (KCL 730 / Aldrich Z677442, Size M)

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de). Splash contact Material: Nitrile rubber Minimum layer thickness: 0,11 mm Break through time: 30 min Material tested:KCL 741 Dermatril® L

Respiratory protection

Not required; except in case of aerosol formation.

Control of environmental exposure

Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a)	Physical state	liquid
b)	Color	yellow
c)	Odor	odorless
d)	Melting point/freezing point	No data available
e)	Initial boiling point and boiling range	> 100 °C
f)	Flammability (solid, gas)	No data available
g)	Upper/lower flammability or explosive limits	No data available
h)	Flash point	275 °C at ca.1.013 hPa - Pensky-Martens closed cup - DIN 51758
i)	Autoignition temperature	No data available
j)	Decomposition	No data available

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temperature

k)	рН	7
I)	Viscosity	Viscosity, kinematic: No data available Viscosity, dynamic: ca.400 mPa.s at 25 °C
m)	Water solubility	0,0002 g/l at 20 °C - OECD Test Guideline 105
n)	Partition coefficient: n-octanol/water	No data available
o)	Vapor pressure	< 1,4 hPa at 20 °C
p)	Density	1,1 g/cm3 at 25 °C
	Relative density	No data available
q)	Relative vapor density	No data available
r)	Particle characteristics	No data available

- s) Explosive properties No data available
- t) Oxidizing properties none

9.2 Other safety information No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Forms explosive mixtures with air on intense heating. A range from approx. 15 Kelvin below the flash point is to be rated as critical.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .

10.3 Possibility of hazardous reactions Violent reactions possible with: Strong oxidizing agents

10.4 Conditions to avoid

Strong heating.

- **10.5 Incompatible materials** No data available
- **10.6 Hazardous decomposition products** In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - Rat - 38.900 mg/kg Remarks: (External MSDS)

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(OECD Test Guideline 403) Remarks: Limit Test (highest concentration to be prepared) Dermal: No data available

Skin corrosion/irritation

Skin - Rabbit Result: No skin irritation - 4 h (OECD Test Guideline 404)

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitization

Maximization Test - Guinea pig Result: Does not cause skin sensitization. (OECD Test Guideline 406)

Germ cell mutagenicity

Test Type: Ames test Test system: Escherichia coli/Salmonella typhimurium Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 471 Result: negative

Carcinogenicity

No data available

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure No data available

Specific target organ toxicity - repeated exposure No data available

Aspiration hazard No data available

11.2 Additional Information

Endocrine disrupting properties

Product:

Assessment

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Hazardous properties cannot be excluded but are unlikely when the product is handled appropriately.

Handle in accordance with good industrial hygiene and safety practice.

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SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish	static test LL50 - Danio rerio (zebra fish) - > 100 mg/l $$ - 96 h (OECD Test Guideline 203)
Toxicity to daphnia and other aquatic invertebrates	EC50 - Daphnia - > 10 mg/l - 48 h Remarks: (above the solubility limit in the test medium) (Lit.)
Toxicity to bacteria	microtox test EC50 - Bacteria - 146 - 774 mg/l - 5 min Remarks: (Lit.)

12.2 Persistence and degradability

Biodegradability

aerobic - Exposure time 28 d Result: > 60 % - Readily biodegradable. (OECD Test Guideline 301F)

- 12.3 Bioaccumulative potential No data available
- **12.4 Mobility in soil** No data 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 Endocrine disrupting properties <u>Product:</u>

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Discharge into the environment must be avoided.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

See www.retrologistik.com for processes regarding the return of chemicals and containers, or contact us there if you have further questions.

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SECTION 14: Transport information					
14.1 UN numb ADR/RID:	•-	IMDG: -	IATA: -		
ADR/RID: IMDG:	r shipping name Not dangerous goo Not dangerous goo Not dangerous goo	ds			
14.3 Transport ADR/RID:	t hazard class(es) -	IMDG: -	IATA: -		
14.4 Packagin ADR/RID:		IMDG: -	IATA: -		
14.5 Environm ADR/RID:		IMDG Marine pollutant: no	IATA: n	0	
14.6 Special p	recautions for use	r			

Further information

Not classified as dangerous in the meaning of transport regulations.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other information

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

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