

Tylopur 6-series

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Issue date: 1/5/2018 Revision date: 10/7/2022 Supersedes: 3/16/2019 Version: 6.1
SDS No: 10896-0476



SE Tylose GmbH & Co. KG

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

1.1. Product identifier

Product form : Substance
Substance name : Tylopur 6-series
Product code : MHPCPHARM
Other means of identification : Tylopur 603, Tylopur 605, Tylopur 606, Tylopur 615, Tylopur 645
Further information : UFI: Not classified = Not applicable

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 : Pharmaceutical additive
Binding agent
Thickener

1.2.2. Uses advised against

Restrictions on use : There is no information available on applications that are not advised

1.3. Details of the supplier of the safety data sheet

Manufacturer

SE Tylose GmbH & Co. KG
Kasteler Straße 45
65203 Wiesbaden
Germany
T + 49 611 962 6309

product.safety@setylose.com - www.setylose.com

E-mail address of competent person responsible for the SDS: sds@gbk-ingelheim.de

Informing department

Customer Service / Sales
T +49 611 962 6442
contact@setylose.com

1.4. Emergency telephone number

Emergency number : +49 (0) 6312 / 84463 (GBK GmbH)

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

Other hazards not contributing to the classification : Dust may form explosive mixture in air. Handle in accordance with good industrial hygiene and safety practice.

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

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SECTION 3: Composition/information on ingredients

3.1. Substances

Comments : A registration number is not available for this substance as the substance or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006.
Name : Tylopur 6-series

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Cellulose, 2-hydroxypropyl methyl ether	CAS-No.: 9004-65-3	> 93,5	Not classified

Comments : When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Call a doctor.
First-aid measures after skin contact : Wash skin with plenty of water.
First-aid measures after eye contact : Rinse immediately with plenty of water, also under the eyelids. Consult an ophthalmologist if irritation persists.
First-aid measures after ingestion : Rinse mouth. If symptoms persist, call a physician.

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

Symptoms/effects after skin contact : May cause sensitisation of susceptible persons by skin contact.
Symptoms/effects after eye contact : May cause eye irritation.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Sand. Alcohol resistant foam. Chemical powder. Carbon dioxide. Water spray.
Unsuitable extinguishing media : No data available.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released. Carbon oxides (CO, CO₂).

5.3. Advice for firefighters

Protection during firefighting : Self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid dust formation. Do not breathe dust. Forms slippery surfaces with water.

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6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

6.1.2. For emergency responders

Protective equipment : Wear recommended personal protective equipment.

6.2. Environmental precautions

Large amounts of the product should not be allowed to enter drains or water courses or be deposited where it can affect ground or surface waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Shovel or sweep up and put in a closed container for disposal. Avoid dust formation.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

Refer to protective measures listed in sections 7 and 8. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Avoid dust formation. Dust may form explosive mixture in air. Keep away from sources of ignition - No smoking.
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Material is hygroscopic. Protect from atmospheric moisture and water.
Information on mixed storage : No special storage requirements.

7.3. Specific end use(s)

Pharmaceutical additive. Binding agent. Thickener.

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

Additional information : Obey TLV for common dust, if applicable

8.1.5. Control banding

No additional information available

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8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Avoid dust formation.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

Not required for normal conditions of use

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Not required for normal conditions of use. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Respiratory protection			
Device	Filter type	Condition	Standard
Breathing apparatus with filter	Type P1	Short term exposure	

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not eat, drink or smoke when using this product. Wash hands immediately after handling the product. Do not breathe dust.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: whitish.
Appearance	: Powder.
Odour	: Odourless.
Odour threshold	: Not available
Melting point	: Not specifically applicable
Freezing point	: Not specifically applicable
Boiling point	: Not specifically applicable
Flammability (solid, gas)	: Not available
Explosive properties	: Product is not explosive. Dust may form explosive mixture in air.
Lower explosive limit (LEL)	: 30 – 80 g/m ³
Upper explosive limit (UEL)	: Not applicable
Flash point	: Not specifically applicable
Auto-ignition temperature	: 170 °C
Decomposition temperature	: Not available
pH	: 5 – 8 20 g/l
pH solution	: Not available

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Viscosity, kinematic	: Not specifically applicable
Viscosity, dynamic	: Not specifically applicable
Solubility	: Water: > 10 g/l @ 20°C
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not specifically applicable
Vapour pressure at 50°C	: Not available
Density	: 1.1 – 1.5 g/cm ³ 20 °C
Relative density	: Not specifically applicable
Relative vapour density at 20°C	: Not specifically applicable
Particle size	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

Minimum ignition energy	: > 10 mJ
Relative evaporation rate (butylacetate=1)	: Not specifically applicable
Bulk density	: 200 – 600 g/l
Combustion class	: 5
p _{max}	: 6-10 bar
Dust explosion category	: ST1
KSt	: < 200 bar*m/s
Ignition temperature	: 360 - 400 °C
MIT (Minimum Ignition Temperature) - Dust cloud	: 360 - 400 °C
MIT (Minimum Ignition Temperature) - Layer	: > 400 °C

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

No decomposition if stored normally.

10.5. Incompatible materials

Strong oxidizing agent.

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 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

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LD50 oral rat	> 2000 mg/kg (OECD 425 method)
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Skin corrosion/irritation	: Not classified pH: 5 – 8 20 g/l
Serious eye damage/irritation	: Not classified pH: 5 – 8 20 g/l
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

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

11.2.2. Other information

Other information : When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
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	> 1000 mg/l (OECD 203 method)
EC50 - Other aquatic organisms [1]	> 1000 mg/l (OECD 209 method)

12.2. Persistence and degradability

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Persistence and degradability	Product is biodegradable. Does not affect the functioning of waste-water treatment plants. In case of loss of large quantities, advice local authorities.
Chemical oxygen demand (COD)	< 1500 mg/g

12.3. Bioaccumulative potential

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Bioaccumulative potential	Not potentially bioaccumulable.
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12.4. Mobility in soil

No additional information available

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12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

12.7. Other adverse effects

Additional information : Do not release undiluted or in higher quantities into the groundwater, sewerage or waters.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
European List of Waste (LoW) code : 16 03 06 - organic wastes other than those mentioned in 16 03 05

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
No dangerous goods as defined by the transport regulations				
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

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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)

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

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
DOT	Department of Transport
TDG	Transportation of Dangerous Goods
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006

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Abbreviations and acronyms:	
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
IARC	International Agency for Research on Cancer
vPvB	Very Persistent and Very Bioaccumulative
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
CAS	CAS (Chemical Abstracts Service) number
IBC-Code	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
ATE	Acute Toxicity Estimate
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
BCF	Bioconcentration factor
MARPOL 73/78	MARPOL 73/78: International Convention for the Prevention of Pollution From Ships
ADG	Transport of Australian Dangerous Goods

Other information : Data of sections 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities. The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge. The delivery specifications are contained in the corresponding product sheet. This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

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 therefore not be construed as guaranteeing any specific property of the product.