

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 26.05.2017

Version 1.1

SECTION 1. Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Catalogue No.	141464
Product name	Parteck® MXP (Polyvinyl alcohol) EMPROVE® ESSENTIAL Ph Eur,JPE,USP
REACH Registration Number	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, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.
CAS-No.	9002-89-5

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

Identified uses	Pharmaceutical production For additional information on uses please refer to the Merck Chemicals portal (www.merckgroup.com).
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1.3 Details of the supplier of the safety data sheet

Company	Merck KGaA * 64271 Darmstadt * Germany * Phone:+49 6151 72-0
Responsible Department	LS-QHC * e-mail: prodsafe@merckgroup.com

1.4 Emergency telephone number	Please contact the regional company representation in your country.
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SECTION 2. Hazards identification**2.1 Classification of the substance or mixture**

This substance is not classified as dangerous according to European Union legislation.

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2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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

Safety data sheet available on request.

2.3 Other hazards

None known.

SECTION 3. Composition/information on ingredients

Chemical nature Polymer
with
Methanol, (as impurity), Volatile.

3.1 Substance

Formula $(C_2H_4O)_n$ (Hill)

Hazardous components (REGULATION (EC) No 1272/2008)

Chemical name (Concentration)

CAS-No.	Registration number	Classification
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Methanol ($\geq 1\%$ - $< 3\%$)

Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

67-56-1	01-2119433307-44-XXXX	Flammable liquid, Category 2, H225 Acute toxicity, Category 3, H301 Acute toxicity, Category 3, H331 Acute toxicity, Category 3, H311 Specific target organ toxicity - single exposure, Category 1, H370
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For the full text of the H-Statements mentioned in this Section, see Section 16.

3.2 Mixture

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Not applicable

SECTION 4. First aid measures

4.1 Description of first aid measures

After inhalation: fresh air.

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

After eye contact: rinse out with plenty of water.

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

We have no description of any toxic symptoms.

4.3 Indication of any immediate medical attention and special treatment needed

No information 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

Combustible.

Risk of dust explosion.

Development of hazardous combustion gases or vapours possible in the event of fire.

5.3 Advice for firefighters

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Special protective equipment for firefighters

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

Further information

Suppress (knock down) gases/vapours/mists with a water spray jet.

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: Avoid inhalation of dusts. Evacuate the danger area, observe emergency procedures, consult an expert.

Advice for emergency responders:

Protective equipment 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 dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

6.4 Reference to other sections

Indications about waste treatment see section 13.

SECTION 7. Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

Observe label precautions.

Hygiene measures

Change contaminated clothing. Wash hands after working with substance.

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7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Tightly closed. Dry.

Recommended storage temperature see product label.

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

Derived No Effect Level (DNEL)

Methanol (67-56-1)

Worker DNEL, acute	Systemic effects	dermal	40 mg/kg Body weight
Worker DNEL, acute	Systemic effects	inhalation	260 mg/m ³
Worker DNEL, acute	Local effects	inhalation	260 mg/m ³
Worker DNEL, longterm	Systemic effects	dermal	40 mg/kg Body weight
Worker DNEL, longterm	Systemic effects	inhalation	260 mg/m ³
Worker DNEL, longterm	Local effects	inhalation	260 mg/m ³
Consumer DNEL, acute	Systemic effects	dermal	8 mg/kg Body weight
Consumer DNEL, acute	Systemic effects	inhalation	50 mg/m ³
Consumer DNEL, acute	Systemic effects	oral	8 mg/kg Body weight
Consumer DNEL, acute	Local effects	inhalation	50 mg/m ³
Consumer DNEL, longterm	Systemic effects	dermal	8 mg/kg Body weight
Consumer DNEL, longterm	Systemic effects	inhalation	50 mg/m ³

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Consumer DNEL, longterm	Systemic effects	oral	8 mg/kg Body weight
Consumer DNEL, longterm	Local effects	inhalation	50 mg/m ³

Predicted No Effect Concentration (PNEC)

Methanol (67-56-1)

PNEC Fresh water	154 mg/l
PNEC Fresh water sediment	570,4 mg/kg
PNEC Marine water	15,4 mg/l
PNEC Soil	23,5 mg/kg
PNEC Sewage treatment plant	100 mg/l

8.2 Exposure controls

Engineering measures

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See section 7.1.

Individual protection measures

Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.

Eye/face protection

Safety glasses

Hand protection

full contact:

Glove material:	Nitrile rubber
Glove thickness:	0,11 mm

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Break through time: > 480 min
splash contact:
Glove material: Nitrile rubber
Glove thickness: 0,11 mm
Break through time: > 480 min

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374, for example KCL 741 Dermatril® L (full contact), KCL 741 Dermatril® L (splash contact).

The breakthrough times stated above were determined by KCL in laboratory tests acc. to EN374 with samples of the recommended glove types.

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).

Respiratory protection

required when dusts are generated.

Recommended Filter type: Filter P 1 (acc. to DIN 3181) for solid particles of inert substances

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

Environmental exposure controls

Do not let product enter drains.

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form solid
Colour white
Odour odourless

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Odour Threshold	Not applicable
pH	No information available.
Melting point	160 - 240 °C
Boiling point	No information available.
Flash point	No information available.
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	No information available.
Upper explosion limit	No information available.
Vapour pressure	No information available.
Relative vapour density	No information available.
Density	No information available.
Relative density	No information available.
Water solubility	soluble in hot water at 20 °C insoluble
Partition coefficient: n-octanol/water	No information available.
Auto-ignition temperature	No information available.

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Product name	Parteck® MXP (Polyvinyl alcohol) EMPROVE® ESSENTIAL Ph Eur,JPE,USP

Decomposition temperature	> 200 °C
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	none

9.2 Other data

Bulk density	400 - 670 kg/m ³
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SECTION 10. Stability and reactivity

10.1 Reactivity

Risk of dust explosion.

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 (decomposition).

10.5 Incompatible materials

no information available

10.6 Hazardous decomposition products

no information available

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SECTION 11. Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity

LD50 Rat: > 2.000 mg/kg

OECD Test Guideline 401

Acute inhalation toxicity

Acute toxicity estimate: > 20 mg/l; 4 h ; vapour

Calculation method

Acute dermal toxicity

Acute toxicity estimate : > 2.000 mg/kg

Calculation method

Skin irritation

Rabbit

Result: No irritation

(External MSDS)

Eye irritation

Rabbit

Result: No eye irritation

(External MSDS)

Sensitisation

This information is not available.

Germ cell mutagenicity

Genotoxicity in vitro

Ames test

Result: negative

(Lit.)

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Carcinogenicity

This information is not available.

Reproductive toxicity

This information is not available.

Teratogenicity

This information is not available.

Specific target organ toxicity - single exposure

This information is not available.

Specific target organ toxicity - repeated exposure

This information is not available.

Aspiration hazard

This information is not available.

11.2 Further information

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

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12. Ecological information

12.1 Toxicity

Toxicity to fish

LC50 Danio rerio (zebra fish): > 5.000 mg/l; 96 h

OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates

EC50 Daphnia (water flea): 8,3 mg/l; 48 h

(External MSDS)

Toxicity to bacteria

EC0 Bacteria: > 8.000 mg/l; 10 d

(Lit.)

12.2 Persistence and degradability

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Biodegradability

> 90 %

OECD Test Guideline 302B

Readily eliminated from water

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects

Discharge into the environment must be avoided.

SECTION 13. Disposal considerations

Waste treatment methods

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

SECTION 14. Transport information

Land transport (ADR/RID)

14.1 - 14.6 Not classified as dangerous in the meaning of transport regulations.

Inland waterway transport (ADN)

Not relevant

Air transport (IATA)

14.1 - 14.6 Not classified as dangerous in the meaning of transport regulations.

Sea transport (IMDG)

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14.1 - 14.6 Not classified as dangerous in the meaning of transport regulations.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not relevant

SECTION 15. Regulatory information

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

EU regulations

Major Accident Hazard SEVESO III
Legislation Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer not regulated

Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC not regulated

Substances of very high concern (SVHC) This product does not contain substances of very high concern according to Regulation (EC) No 1907/2006 (REACH), Article 57 above the respective regulatory concentration limit of ≥ 0.1 % (w/w).

National legislation

Storage class 10 - 13

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

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SECTION 16. Other information

Full text of H-Statements referred to under sections 2 and 3.

H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H331	Toxic if inhaled.
H370	Causes damage to organs.

Training advice

Provide adequate information, instruction and training for operators.

Key or legend to abbreviations and acronyms used in the safety data sheet

Used abbreviations and acronyms can be looked up at www.wikipedia.org.

Regional representation

This information is given on the authorised Safety Data Sheet for your country.

The information contained herein is based on the present state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.