



MATERIAL SAFETY DATA SHEET

according to the Hazard Communication Standard (29 CFR 1910.1200)

Revision Date 09/28/2012

Version 1.1

SECTION 1. Identification

Product identifier

Product number	100419
Product name	Parteck® M 200 (Mannitol) suitable for use as excipient EMPROVE® exp Ph Eur,BP,JP,USP,E 421

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

Identified uses	Pharmaceutical production
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Details of the supplier of the safety data sheet

Company	EMD Millipore Corporation 290 Concord Road, Billerica, MA 01821, United States of America SDS Phone Support: +1-978-715-1335 General Inquiries: +1-978-751-4321 Monday to Friday, 9:00 AM to 4:00 PM Eastern Time (GMT-5) e-mail: mm_sds@merckgroup.com
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Emergency telephone	800-424-9300 CHEMTREC (USA) +1-703-527-3887 CHEMTREC (International) 24 Hours/day; 7 Days/week
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SECTION 2. Hazards identification

GHS-Labeling

Not a dangerous substance according to GHS.

OSHA Hazards

While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this MSDS contains valuable information critical to the safe handling and proper use of the product. This MSDS should be retained and available for employees and other users of this product.

Other hazards

None known.

SECTION 3. Composition/information on ingredients

Formula	C ₆ H ₁₄ O ₆ (Hill)
CAS-No.	69-65-8
Molar mass	182.17 g/mol

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Remarks No hazardous ingredients according to the OSHA Hazard
Communication Standard 29 CFR 1910.1200.

SECTION 4. First aid measures

Description of first-aid measures

Inhalation

After inhalation: fresh air.

Skin contact

After skin contact: wash off with plenty of water. Remove contaminated clothing.

Eye contact

After eye contact: rinse out with plenty of water.

Ingestion

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

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

Diarrhea, Nausea, Vomiting

Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media

Water, Carbon dioxide (CO₂), Foam, Dry powder

Unsuitable extinguishing media

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

Special hazards arising from the substance or mixture

Combustible material, Development of hazardous combustion gases or vapors possible in the event of fire.

Risk of dust explosion.

Advice for firefighters

Special protective equipment for fire-fighters

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

SECTION 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid generation of dusts; do not inhale dusts. Evacuate the danger area, observe emergency procedures, consult an expert.

Advice for emergency responders: Protective equipment see section 8.

Environmental precautions

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No special precautionary measures necessary.

Methods and materials for containment and cleaning up

Observe possible material restrictions (see sections 7 and 10).
Take up dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

SECTION 7. Handling and storage

Precautions for safe handling

Observe label precautions.

Conditions for safe storage, including any incompatibilities

Tightly closed. Dry.

Storage temperature: no restrictions.

SECTION 8. Exposure controls/personal protection

Exposure limit(s)

Contains no substances with occupational exposure limit values.

Engineering measures

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

Individual protection measures

Protective clothing should be selected specifically for the workplace, depending on concentration and quantity of the hazardous substances handled. The chemical resistance of the protective equipment should be inquired at the respective supplier.

Hygiene measures

Change contaminated clothing. Wash hands after working with substance.

Eye/face protection

Safety glasses

Hand protection

Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Recommended:

full contact:

Glove material:	Nitrile rubber
Glove thickness:	0.11 mm
Break through time:	> 480 min

splash contact:

Glove material:	Nitrile rubber
Glove thickness:	0.11 mm
Break through time:	> 480 min

Respiratory protection

required when dusts are generated.

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Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

SECTION 9. Physical and chemical properties

Physical state	solid
Color	white
Odor	odorless
Odor Threshold	No information available.
pH	5 - 7 at 100 g/l 68 °F (20 °C)
Melting point	327 - 336 °F (164 - 169 °C)
Boiling point/boiling range	554 - 563 °F (290 - 295 °C) at 4 hPa
Flash point	not applicable
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	125 g/m ³
Upper explosion limit	not applicable
Vapor pressure	No information available.
Relative vapor density	No information available.
Relative density	No information available.
Water solubility	213 g/l at 77 °F (25 °C)
Partition coefficient: n-octanol/water	log Pow: -3.1 (experimental) (Lit.) Bioaccumulation is not expected (log Pow <1).
Autoignition temperature	No information available.
Decomposition temperature	No information available.

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Viscosity, dynamic	No information available.
Sublimation point	266 °F (130 °C)
Ignition temperature	770 °F (410 °C)
Bulk density	ca. 400 - 500 kg/m ³

SECTION 10. Stability and reactivity

Reactivity

Risk of dust explosion.

Chemical stability

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

Possibility of hazardous reactions

Violent reactions possible with:

Strong oxidizing agents, Strong acids, strong alkalis

Conditions to avoid

no information available

Incompatible materials

no information available

Hazardous decomposition products

no information available

SECTION 11. Toxicological information

Information on toxicological effects

Likely route of exposure

Eye contact, Skin contact, Ingestion

Acute oral toxicity

LD50 rat: 13,500 mg/kg (RTECS)

Genotoxicity in vivo

Mutagenicity (mammal cell test): micronucleus.

Result: negative

(National Toxicology Program)

Mutagenicity (mammal cell test): chromosome aberration.

Result: negative

(National Toxicology Program)

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Genotoxicity in vitro

Ames test

Salmonella typhimurium

Result: negative

(National Toxicology Program)

Specific target organ systemic toxicity - single exposure

The substance or mixture is not classified as specific target organ toxicant, single exposure.

Specific target organ systemic toxicity - repeated exposure

The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration hazard

Regarding the available data the classification criteria are not fulfilled.

Carcinogenicity

IARC

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

ACGIH

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

Further information

After swallowing of large amounts:

Nausea, Vomiting, Diarrhea

Further data:

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12. Ecological information

Ecotoxicity

No information available.

Persistence and degradability

Theoretical oxygen demand (ThOD)

1,150 mg/g

(Lit.)

Ratio BOD/ThBOD

BOD5 59 %

(Lit.)

Ratio COD/ThBOD

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87 %
(Lit.)

Bioaccumulative potential

Partition coefficient: n-octanol/water

log Pow: -3.1

(experimental)

(Lit.) Bioaccumulation is not expected (log Pow <1).

Mobility in soil

No information available.

Other adverse effects

Additional ecological information

We have no quantitative data concerning the ecological effects of this product.

Further information on ecology

No ecological problems are to be expected when the product is handled and used with due care and attention.

SECTION 13. Disposal considerations

The information presented only applies to the material as supplied. The identification based on characteristic(s) or listing may not apply if the material has been used or otherwise contaminated. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable regulations. Disposal should be in accordance with applicable regional, national and local laws and regulations.

SECTION 14. Transport information

Land transport (DOT)

Not classified as dangerous in the meaning of transport regulations.

Air transport (IATA)

Not classified as dangerous in the meaning of transport regulations.

Sea transport (IMDG)

Not classified as dangerous in the meaning of transport regulations.

SECTION 15. Regulatory information

United States of America

OSHA Hazards

No OSHA Hazards

This information is based on 29 CFR 1910.1200 criteria prior to adoption of the GHS, and may deviate from the GHS information on the label and in section 2.

TSCA list

Not relevant

SARA 311/312 Hazards

No SARA Hazards

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Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

Massachusetts Right To Know

Remarks

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Ingredients

D-mannitol

New Jersey Right To Know

Ingredients

D-mannitol

California Prop 65 Components

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

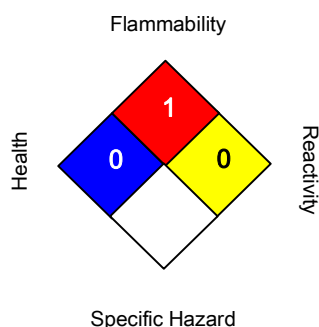
Notification status

TSCA: On TSCA Inventory

DSL: All components of this product are on the Canadian DSL.

SECTION 16. Other information

National Fire Protection Association (U.S.A)



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.

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The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to appropriate safety precautions. It does not represent a warranty of any product properties and we assume no liability for any loss or injury which may result from the use of this information. Users should conduct their own investigations to determine the suitability of the information.

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