

according to the Global Harmonized System (and with all of the information required by the HPR)

Revision Date 12/14/2018

Version 1.6

#### **SECTION 1.Identification**

#### **Product identifier**

Product number 137045

Product name Lactose monohydrate powder EMPROVE® EXPERT Ph

Eur, BP, NF, JP

CAS-No. 10039-26-6

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

Identified uses Pharmaceutical production, Reagent for analysis, Cosmetic

raw material

# Details of the supplier of the safety data sheet

Company Millipore (Canada) Ltd. | 2149 Winston Park Dr. | Oakville |

Ontario L6H 6J8 | Canada | General Inquiries: +1 905 829 9500 | Monday to Friday, 9:00 AM to 4:00 PM Eastern Time

(GMT-5)

MilliporeSigma is a business of Merck KGaA, Darmstadt,

Germany.

**Emergency telephone** 800-424-9300 CHEMTREC (USA)

+1-703-527-3887 CHEMTREC (International)

24 Hours/day; 7 Days/week

# **SECTION 2. Hazards identification**

#### **GHS-Labeling**

Not a dangerous substance according to GHS.

#### Other hazards

None known.

#### **SECTION 3. Composition/information on ingredients**

Formula  $C_{12}H_{22}O_{11} * H_2O (Hill)$ 

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Molar mass 360.32 g/mol

Remarks WHMIS hazardous composition: No ingredients are

hazardous according to the HPR criteria.

#### **SECTION 4. First aid measures**

### **Description of first-aid measures**

Inhalation

After inhalation: fresh air.

Skin contact

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin

with water/ shower.

Eye contact

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

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

We have no description of any toxic symptoms.

### Indication of any immediate medical attention and special treatment needed

No information available.

### **SECTION 5. Fire-fighting measures**

#### **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.

### Special hazards arising from the substance or mixture

Combustible.

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

### **Advice for firefighters**

Special protective equipment for fire-fighters

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

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Further information

none

#### SECTION 6. Accidental release measures

# 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.

### **Environmental precautions**

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.

Store at  $+15^{\circ}$ C to  $+25^{\circ}$ C ( $+59^{\circ}$ F to  $+77^{\circ}$ F).

## **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



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Hand protection

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

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 and supplied by us as well as to the purpose specified by us. 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

The entrepeneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are performed according to the instructions of the producer.

These measures have to be properly documented.

#### **SECTION 9. Physical and chemical properties**

Physical state solid

Color white

Odor odorless

Odor Threshold Not applicable

4.0 - 6.5pН

> at 100 g/l 68 °F (20 °C)



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Product name Lactose monohydrate powder EMPROVE® EXPERT Ph Eur,BP,NF,JP

Melting point 396 °F (202 °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.

Vapor pressure No information available.

Relative vapor density No information available.

Density No information available.

Relative density No information available.

Water solubility 161 g/l

at 68 °F (20 °C)

Partition coefficient: n-

octanol/water

log Pow: -5.03 (calculated)

(anhydrous substance) Bioaccumulation is not

expected.

Autoignition temperature No information available.

Decomposition temperature No information available.

Viscosity, dynamic No information available.

Explosive properties Not classified as explosive.

Oxidizing properties none

Ignition temperature 734 °F (390 °C)

Bulk density ca.500 kg/m3



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### **SECTION 10. Stability and reactivity**

### Reactivity

The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

### **Chemical stability**

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

# Possibility of hazardous reactions

Violent reactions possible with:

Strong oxidizing agents

#### **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: > 10,000 mg/kg (anhydrous substance) (RTECS)

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

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	than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.	
OSHA	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.	
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**

No toxic effects are to be expected when the product is handled appropriately. Substances which occur in nature

Handle in accordance with good industrial hygiene and safety practice.

# **SECTION 12. Ecological information**

# **Ecotoxicity**

No information available.

# Persistence and degradability

No information available.

# **Bioaccumulative potential**

Partition coefficient: n-octanol/water

log Pow: -5.03 (calculated)

(anhydrous substance) Bioaccumulation is not expected.

#### Mobility in soil

No information available.

### **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.



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### **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**

#### Canada

This product has been classified in accordance with the hazard criteria of the Hazardous Products Regulations (HPR) and the SDS contains all the information required by the HPR.

#### **Notification status**

TSCA: All components of the product are listed in the TSCA-

inventory.

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

### **SECTION 16. Other information**

### 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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