

SAFETY DATA SHEET

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

Revision Date 06/15/2018

Version 1.5

SECTION 1. Identification**Product identifier**

Product number	108346
Product name	D(+)-Glucose monohydrate suitable for use as excipient EMPROVE® exp Ph Eur,BP,USP
CAS-No.	14431-43-7

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

Identified uses	Pharmaceutical production, Cosmetic raw material
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Details of the supplier of the safety data sheet

Company	Millipore (Canada) Ltd 109 Woodbine Downs Blvd. Unit 5 Etobicoke Ontario M9W 6Y1 Canada General Inquiries: +1 800-645-5476 Monday to Friday, 9:00 AM to 4:00 PM Eastern Time (GMT-5) MilliporeSigma is a business of Merck KGaA, Darmstadt, Germany.
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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.

Other hazards

None known.

SECTION 3. Composition/information on ingredients

Formula	$C_6H_{12}O_6 \cdot H_2O$ (Hill)
Molar mass	198.17 g/mol
Remarks	WHMIS hazardous composition: No ingredients are hazardous according to the CPR criteria.

SECTION 4. First aid measures**Description of first-aid measures**

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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.

Risk of dust explosion.

Advice for firefighters

Special protective equipment for fire-fighters

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

Further information

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

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

Do not let product enter drains.

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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.

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°C to +25°C (+59°F to +77°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

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).

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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 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	colorless
Odor	odorless
Odor Threshold	No information available.
pH	6 - 7 at 100 g/l 68 °F (20 °C)
Melting point	ca. 181 °F (83 °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	1,000 g/l at 68 °F (20 °C)
Partition coefficient: n-octanol/water	log Pow: -3.29 (anhydrous substance) Bioaccumulation is not expected. (Lit.)

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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	ca. 932 °F (500 °C)
Bulk density	ca.630 kg/m ³

SECTION 10. Stability and reactivity

Reactivity

Risk of dust explosion.

Chemical stability

releases water of crystallization when heated.

Possibility of hazardous reactions

Exothermic reaction 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: 25,800 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.

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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 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

Substances which occur in nature

Substance which occurs in the human body under physiological conditions.

Our own experience has provided no indication of any hazardous potential.

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12. Ecological information

Ecotoxicity

Toxicity to fish

LC0 fish: 60,000 mg/l(anhydrous substance) (External MSDS)

Persistence and degradability

Biodegradability

48 %; 5 d

OECD Test Guideline 301D
(External MSDS)

Readily biodegradable.

Bioaccumulative potential

Partition coefficient: n-octanol/water

log Pow: -3.29

(anhydrous substance) Bioaccumulation is not expected. (Lit.)

Mobility in soil

No information available.

Additional ecological information

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

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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

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.

Revision Date 06/15/2018

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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