

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

Revision Date 02/21/2019

Version 1.6

SECTION 1.Identification

Product identifier

Product number 108486

Product name Urea cryst. EMPROVE® ESSENTIAL Ph Eur, BP, USP, JP

CAS-No. 57-13-6

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

Identified uses Pharmaceutical production, 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 CO(NH₂)₂ CH₄N₂O (Hill)

Molar mass 60.06 g/mol

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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

Nausea, Vomiting, Cough, Shortness of breath

Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media

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

Special hazards arising from the substance or mixture

Not combustible.

Risk of dust explosion.

Ambient fire may liberate hazardous vapors.

Fire may cause evolution of:

Ammonia, nitrous gases

Advice for firefighters



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Special protective equipment for fire-fighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

Further information

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

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 $+15^{\circ}$ C to $+30^{\circ}$ C ($+59^{\circ}$ F to $+86^{\circ}$ 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.

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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).

Respiratory protection

required when dusts are generated.

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

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 ammoniacal

Odor Threshold Ammonia



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pH ca. 9

at 100 g/l 68 °F (20 °C)

Melting point 271 °F (133 °C)

Method: DIN 53181

Boiling point/boiling range decomposition below boiling point

Flash point Not applicable

Evaporation rate No information available.

Flammability (solid, gas) The product is not flammable.

Lower explosion limit No information available.

Upper explosion limit No information available.

Vapor pressure < 0.1 hPa

at 68 °F (20 °C)

Relative vapor density No information available.

Density 1.34 g/cm3

at 68 °F (20 °C)

Relative density No information available.

Water solubility ca.1,000 g/l

at 68 °F (20 °C)

Partition coefficient: n-

octanol/water

log Pow: -1.59 (25 °C) OECD Test Guideline 107

Bioaccumulation is not expected.

Autoignition temperature No information available.

Decomposition temperature > 270 °F (> 132 °C)

Viscosity, dynamic No information available.

Explosive properties Not classified as explosive.



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Oxidizing properties none

Ignition temperature Not applicable

Bulk density 720 - 760 kg/m3

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

Exothermic reaction with:

metallic chlorides, Chlorites, chromates/perchromates, Fluorine, nitrates, strong oxidizing agents, hydrogen peroxide, TITANIUM TETRACHLORIDE

Generates dangerous gases or fumes in contact with:

bases, chlorinated solvents

Risk of explosion/exothermic reaction with:

ammonium nitrate, calcium hypochlorite, Chlorine, chromyl chloride, Nitroso compound, sodium hypochlorite, nitrosyl compounds, phosphorus pentachloride, perchlorates, nitrites, Nitro compounds

Conditions to avoid

Strong heating (decomposition).

Incompatible materials

various plastics

Hazardous decomposition products

in the event of fire: See section 5.

SECTION 11. Toxicological information Information on toxicological effects

Likely route of exposure
Eye contact, Skin contact, Ingestion



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Acute oral toxicity

LD50 Rat: 8,471 mg/kg (RTECS)

Symptoms: Nausea, Vomiting

Acute dermal toxicity LD50 Rat: 8,200 mg/kg

(IUCLID)

Skin irritation

Rabbit

Result: No irritation

(IUCLID)

Eye irritation

Rabbit

Result: No eye irritation

(IUCLID)

Sensitization

Human experience
Result: negative

(IUCLID)

Genotoxicity in vitro

Ames test

Result: negative

(IUCLID)

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 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

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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

No toxic effects are to be expected when the product is handled appropriately.

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12. Ecological information

Ecotoxicity

Toxicity to fish

LC50 Leuciscus idus (Golden orfe): > 6,810 mg/l; 96 h (IUCLID)

Toxicity to daphnia and other aquatic invertebrates

EC50 Daphnia magna (Water flea): > 10,000 mg/l; 24 h (IUCLID)

Toxicity to algae

IC5 Scenedesmus quadricauda (Green algae): > 10,000 mg/l; 7 d (Lit.) (maximum permissible toxic concentration)

Toxicity to bacteria

EC5 Pseudomonas putida: > 10,000 mg/l; 16 h (Lit.) (maximum permissible toxic concentration)

Persistence and degradability

Biodegradability

96 %; 16 d

OECD Test Guideline 302B

Readily eliminated from water

Bioaccumulative potential

Partition coefficient: n-octanol/water

log Pow: -1.59 (25 °C) OECD Test Guideline 107

Bioaccumulation is not expected.

Mobility in soil

No information available.

Additional ecological information

Discharge into the environment must be avoided.



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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.



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