

according to Regulation (EC) No. 1907/2006

Revision Date 30.07.2018

Version 1.8

SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Catalogue No. 102367

Product name Magnesium chloride hexahydrate cryst. EMPROVE® API Ph

Eur, BP, JPC, USP

REACH Registration Number 01-2119485597-19-XXXX

CAS-No. 7791-18-6

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

Identified uses Pharmaceutical production, Cosmetic raw material

For additional information on uses please refer to the Merck Chemicals

portal (www.merckgroup.com).

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

Please contact the regional company representation in your country.

number

SECTION 2. Hazards identification

2.1 Classification of the substance or mixture

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

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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

according to Regulation (EC) No. 1907/2006

Catalogue No. 102367

Product name Magnesium chloride hexahydrate cryst. EMPROVE® API Ph

Eur, BP, JPC, USP

2.3 Other hazards

None known.

SECTION 3. Composition/information on ingredients

3.1 Substance

Formula MgCl₂ * 6 H₂O Cl₂Mg * 6 H₂O (Hill)

EC-No. 232-094-6 Molar mass 203,30 g/mol

Remarks No disclosure requirement according to Regulation (EC) No.

1907/2006.

3.2 Mixture

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. Remove contact lenses.

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

irritant effects, respiratory paralysis, Diarrhoea, Nausea, Vomiting, cardiovascular disorders, muscular weakness, Tiredness, paralysis symptoms

4.3 Indication of any immediate medical attention and special treatment needed

No information available.

according to Regulation (EC) No. 1907/2006

Catalogue No. 102367

Product name Magnesium chloride hexahydrate cryst. EMPROVE® API Ph

Eur, BP, JPC, USP

SECTION 5. Firefighting measures

5.1 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.

5.2 Special hazards arising from the substance or mixture

Not combustible.

Ambient fire may liberate hazardous vapours.

Fire may cause evolution of:

Hydrogen chloride gas

5.3 Advice for firefighters

Special protective equipment for firefighters

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/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.

according to Regulation (EC) No. 1907/2006

Catalogue No. 102367

Product name Magnesium chloride hexahydrate cryst. EMPROVE® API Ph

Eur, BP, JPC, USP

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.

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

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.

according to Regulation (EC) No. 1907/2006

Catalogue No. 102367

Product name Magnesium chloride hexahydrate cryst. EMPROVE® API Ph

Eur, BP, JPC, USP

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

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 entrepeneur 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.

according to Regulation (EC) No. 1907/2006

Catalogue No. 102367

Product name Magnesium chloride hexahydrate cryst. EMPROVE® API Ph

Eur, BP, JPC, USP

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 colourless

Odour odourless

Odour Threshold Not applicable

pH 4,5 - 7,0

at 50 g/l 20 °C

Melting point ca. 117 °C

(decomposition)

Boiling point/boiling range Not applicable

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.

according to Regulation (EC) No. 1907/2006

Catalogue No. 102367

Product name Magnesium chloride hexahydrate cryst. EMPROVE® API Ph

Eur, BP, JPC, USP

Vapour pressure No information available.

Relative vapour density No information available.

Density ca.1,57 g/cm3

at 20 °C

Relative density No information available.

Water solubility 468,7 g/l

at 20 °C

Method: OECD Test Guideline 105

Partition coefficient: n-

octanol/water

No information available.

Auto-ignition temperature No information available.

Decomposition temperature > 117 °C

Elimination of water of crystallisation

Viscosity, dynamic No information available.

Explosive properties Not classified as explosive.

Oxidizing properties none

9.2 Other data

Ignition temperature not combustible

SECTION 10. Stability and reactivity

10.1 Reactivity

See section 10.3

according to Regulation (EC) No. 1907/2006

Catalogue No. 102367

Product name Magnesium chloride hexahydrate cryst. EMPROVE® API Ph

Eur, BP, JPC, USP

10.2 Chemical stability

releases water of crystallisation when heated.

10.3 Possibility of hazardous reactions

no information available

10.4 Conditions to avoid

Strong heating (decomposition).

10.5 Incompatible materials

no information available

10.6 Hazardous decomposition products

in the event of fire: See section 5.

SECTION 11. Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity

LD50 Rat: > 2.000 mg/kg OECD Test Guideline 423

Acute inhalation toxicity

Symptoms: slight mucosal irritations

Acute dermal toxicity

LD50 Rat: > 2.000 mg/kg OECD Test Guideline 402 (anhydrous substance)

according to Regulation (EC) No. 1907/2006

Catalogue No. 102367

Product name Magnesium chloride hexahydrate cryst. EMPROVE® API Ph

Eur, BP, JPC, USP

Skin irritation

Humans

Result: No skin irritation Human Skin Model Test

(ECHA)

Eye irritation

Rabbit

Result: No eye irritation OECD Test Guideline 405

Sensitisation

Maximisation Test Guinea pig

Result: negative

Method: OECD Test Guideline 406

Germ cell mutagenicity

Genotoxicity in vitro

Ames test

Bacillus subtilis

Result: negative

(Lit.)

Mutagenicity (mammal cell test): chromosome aberration.

Human lymphocytes

Result: negative

Method: OECD Test Guideline 473

In vitro mammalian cell gene mutation test

Mouse lymphoma test

Result: negative

Method: OECD Test Guideline 476

The value is given in analogy to the following substances: magnesium chloride

according to Regulation (EC) No. 1907/2006

Catalogue No. 102367

Product name Magnesium chloride hexahydrate cryst. EMPROVE® API Ph

Eur, BP, JPC, USP

Carcinogenicity

This information is not available.

Reproductive toxicity

Application Route: Oral

Rat

Method: OECD Test Guideline 422

Teratogenicity

Application Route: Oral

Rat

Number of exposures: daily

Method: OECD Test Guideline 414

Specific target organ toxicity - single exposure

This information is not available.

Specific target organ toxicity - repeated exposure

This information is not available.

Repeated dose toxicity

Rat

male and female

Oral

54 d

daily

NOAEL: > 1.000 mg/kg
OECD Test Guideline 422

Subacute toxicity

Aspiration hazard

This information is not available.

11.2 Further information

After uptake of large quantities:

Metal-fume fever after inhalation of large quantities.

according to Regulation (EC) No. 1907/2006

Catalogue No. 102367

Product name Magnesium chloride hexahydrate cryst. EMPROVE® API Ph

Eur, BP, JPC, USP

Nausea, Vomiting, Diarrhoea

Systemic effects:

drop in blood pressure, Cardiac irregularities, muscular weakness, paralysis symptoms,

Tiredness

After absorption of large quantities:

respiratory paralysis, cardiovascular disorders

However, when the product is handled appropriately, hazardous effects are unlikely to occur.

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12. Ecological information

12.1 Toxicity

Toxicity to fish

LC50 Pimephales promelas (fathead minnow): 2.120 mg/l; 96 h

Analytical monitoring: yes

(anhydrous substance) (ECHA)

Toxicity to daphnia and other aquatic invertebrates

static test LC50 Daphnia magna (Water flea): 548,4 mg/l; 48 h

Analytical monitoring: yes

(ECHA)

Toxicity to algae

Growth rate EC50 Desmodesmus subspicatus (green algae): > 100 mg/l; 72 h

Analytical monitoring: yes OECD Test Guideline 201

Growth rate NOEC Desmodesmus subspicatus (green algae): 100 mg/l; 72 h

Analytical monitoring: yes OECD Test Guideline 201

Toxicity to bacteria

static test EC50 activated sludge: > 900 mg/l; 3 h

OECD Test Guideline 209

static test NOEC activated sludge: 900 mg/l; 3 h

OECD Test Guideline 209

according to Regulation (EC) No. 1907/2006

Catalogue No. 102367

Product name Magnesium chloride hexahydrate cryst. EMPROVE® API Ph

Eur, BP, JPC, USP

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) semi-static test EC10 Daphnia magna (Water flea): 321 mg/l; 21 d Analytical monitoring: yes

(ECHA)

12.2 Persistence and degradability

Biodegradability

The methods for determining the biological degradability are not applicable to inorganic substances.

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

Additional ecological information

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)

according to Regulation (EC) No. 1907/2006

Catalogue No. 102367

Product name Magnesium chloride hexahydrate cryst. EMPROVE® API Ph

Eur, BP, JPC, USP

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

regulations.

Sea transport (IMDG)

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 not regulated

deplete the ozone layer

Regulation (EC) No 850/2004 of the European not regulated

Parliament and of the Council of 29 April 2004 on

persistent organic pollutants and amending

Directive 79/117/EEC

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 \geq 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.

according to Regulation (EC) No. 1907/2006

Catalogue No. 102367

Product name Magnesium chloride hexahydrate cryst. EMPROVE® API Ph

Eur, BP, JPC, USP

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.

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.