

according to Regulation (EC) No. 1907/2006

Revision Date 14.07.2018

Version 12.3

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

1.1 Product identifier

Catalogue No. 1.2290

Product name Iron(II) sulfate heptahydrate cryst., EMPROVE® ESSENTIAL Ph

Eur, BP, USP, FCC

REACH Registration Number 01-2119513203-57-XXXX

CAS-No. 7782-63-0

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

Identified uses Pharmaceutical production

For additional information on uses please refer to the Neutron Pharma

Chemicals portal (www.Neutronpharmachemical.com).

1.3 Details of the supplier of the safety data sheet

NEUTRON PHARMACHEMICAL CO Company

98, 9th Floor, Borjsaz Building, Azadi Ave, Tehran, Iran.

T 021-66906732-3 - F 021-66581408 72-0 Responsible Department info@neutronpharmachemical.com

www.neutronpharmachemical.com

1.4 Emergency telephone

number

Please contact the regional company representation in your country.

SECTION 2. Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4, Oral, H302

Skin irritation, Category 2, H315

Eye irritation, Category 2, H319

For the full text of the H-Statements mentioned in this Section, see Section 16.

according to Regulation (EC) No. 1907/2006

Catalogue No. 1.2290

Product name Iron(II) sulfate heptahydrate cryst., EMPROVE® ESSENTIAL Ph

Eur, BP, USP, FCC

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word

Warning

Hazard statements

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Precautionary statements

Response

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Reduced labelling (≤125 ml)

Hazard pictograms



Signal word
Warning

Index-No. 026-003-00-7

2.3 Other hazards

None known.

according to Regulation (EC) No. 1907/2006

Catalogue No. 1.2290

Product name Iron(II) sulfate heptahydrate cryst., EMPROVE® ESSENTIAL Ph

Eur, BP, USP, FCC

SECTION 3. Composition/information on ingredients

3.1 Substance

Formula FeSO₄ * 7H₂O FeO₄S * 7H₂O (Hill)

Index-No. 026-003-00-7

EC-No. 231-753-5

Molar mass 278,02 g/mol

Hazardous components (REGULATION (EC) No 1272/2008)

Chemical name (Concentration)

CAS-No. Registration number Classification Iron(II) sulphate heptahydrate (>= 80 % - <= 100 %)

7782-63-0 01-2119513203-57-

XXXX Acute toxicity, Category 4, H302

Skin irritation, Category 2, H315 Eye irritation, Category 2, H319

For the full text of the H-Statements mentioned in this Section, see Section 16.

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. Call in ophthalmologist. Remove contact lenses.

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

according to Regulation (EC) No. 1907/2006

Catalogue No. 1.2290

Product name Iron(II) sulfate heptahydrate cryst., EMPROVE® ESSENTIAL Ph

Eur, BP, USP, FCC

4.2 Most important symptoms and effects, both acute and delayed

Diarrhoea, Bloody vomiting

The following applies to soluble iron compounds: nausea and vomiting after swallowing. The absorption of large quantities is followed by cardiovascular disorders. Toxic effect on liver and kidneys.

irritant effects

4.3 Indication of any immediate medical attention and special treatment needed

No information available.

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:

Sulphur oxides

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.

according to Regulation (EC) No. 1907/2006

Catalogue No. 1.2290

Product name Iron(II) sulfate heptahydrate cryst., EMPROVE® ESSENTIAL Ph

Eur, BP, USP, FCC

SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid inhalation of dusts. Avoid substance contact. Ensure adequate ventilation. 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.

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

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Protected from light.

Tightly closed. Dry.

according to Regulation (EC) No. 1907/2006

Catalogue No. 1.2290

Product name Iron(II) sulfate heptahydrate cryst., EMPROVE® ESSENTIAL Ph

Eur, BP, USP, FCC

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.

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

according to Regulation (EC) No. 1907/2006

Catalogue No. 1.2290

Product name Iron(II) sulfate heptahydrate cryst., EMPROVE® ESSENTIAL Ph

Eur, BP, USP, FCC

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).

Other protective equipment

protective clothing

Respiratory protection

required when dusts are generated.

Recommended Filter type: Filter B-(P2)

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.

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 blue green

Odour odourless

Odour Threshold Not applicable

according to Regulation (EC) No. 1907/2006

Catalogue No. 1.2290

Product name Iron(II) sulfate heptahydrate cryst., EMPROVE® ESSENTIAL Ph

Eur,BP,USP,FCC

pH 3-4

at 50 g/l

20 °C

Melting point > 60 °C

Elimination of water of crystallisation

Boiling point No information available.

Flash point does not flash

Evaporation rate No information available.

Flammability (solid, gas) No information available.

Lower explosion limit Not applicable

Upper explosion limit Not applicable

Vapour pressure No information available.

Relative vapour density No information available.

Density 1,89 g/cm3

at 20 $^{\circ}\text{C}$

Relative density No information available.

Water solubility ca.400 g/l

at 20 °C

Partition coefficient: n-

octanol/water

No information available.

according to Regulation (EC) No. 1907/2006

Catalogue No. 1.2290

Product name Iron(II) sulfate heptahydrate cryst., EMPROVE® ESSENTIAL Ph

Eur, BP, USP, FCC

Auto-ignition temperature No information available.

Decomposition temperature > 300 °C

Viscosity, dynamic Not applicable

Explosive properties Not classified as explosive.

Oxidizing properties none

9.2 Other data

Ignition temperature not combustible

Bulk density ca.600 kg/m3

SECTION 10. Stability and reactivity

10.1 Reactivity

See section 10.3

10.2 Chemical stability

Sensitivity to light

releases water of crystallisation when heated.

10.3 Possibility of hazardous reactions

increased reactivity with:

Bases, Oxidizing agents

10.4 Conditions to avoid

Exposure to moisture

10.5 Incompatible materials

no information available

10.6 Hazardous decomposition products

according to Regulation (EC) No. 1907/2006

Catalogue No. 1.2290

Product name Iron(II) sulfate heptahydrate cryst., EMPROVE® ESSENTIAL Ph

Eur, BP, USP, FCC

in the event of fire: See section 5.

SECTION 11. Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity

LD50 Rat: 319 mg/kg

(anhydrous substance) (Lit.)

absorption

Acute inhalation toxicity

Symptoms: Possible damages:, mucosal irritations

Acute dermal toxicity

This information is not available.

Skin irritation

Causes skin irritation.

Eye irritation

Causes serious eye irritation.

Sensitisation

In animal experiments:

Result: negative

(IUCLID)

Germ cell mutagenicity

Genotoxicity in vitro

Ames test

Result: negative

(Lit.)

according to Regulation (EC) No. 1907/2006

Catalogue No. 1.2290

Product name Iron(II) sulfate heptahydrate cryst., EMPROVE® ESSENTIAL Ph

Eur, BP, USP, FCC

Carcinogenicity

This information is not available.

Reproductive toxicity

This information is not available.

Teratogenicity

This information is not available.

Specific target organ toxicity - single exposure

This information is not available.

Specific target organ toxicity - repeated exposure

This information is not available.

Aspiration hazard

This information is not available.

11.2 Further information

Systemic effects:

After swallowing of large amounts:

Bloody vomiting, Diarrhoea, drop in blood pressure

The following applies to soluble iron compounds: nausea and vomiting after swallowing. The absorption of large quantities is followed by cardiovascular disorders. Toxic effect on liver and kidneys.

Other dangerous properties can not be excluded.

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12. Ecological information

12.1 Toxicity

Toxicity to fish

LC50 Poecilia reticulata (guppy): 925 mg/l; 96 h

(IUCLID)

Toxicity to daphnia and other aquatic invertebrates

EC50 Daphnia magna (Water flea): 152 mg/l; 48 h

(anhydrous substance) (IUCLID)

according to Regulation (EC) No. 1907/2006

Catalogue No. 1.2290

Product name Iron(II) sulfate heptahydrate cryst., EMPROVE® ESSENTIAL Ph

Eur, BP, USP, FCC

Toxicity to bacteria

EC0 Pseudomonas fluorescens: 100 mg/l; 24 h

(anhydrous substance) (IUCLID)

12.2 Persistence and degradability

No information available.

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)

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

regulations.

Sea transport (IMDG)

according to Regulation (EC) No. 1907/2006

Catalogue No. 1.2290

Product name Iron(II) sulfate heptahydrate cryst., EMPROVE® ESSENTIAL Ph

Eur, BP, USP, FCC

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

Occupational restrictions Take note of Dir 94/33/EC on the protection of young people at

work. Observe work restrictions regarding maternity protection in accordance to Dir 92/85/EEC or stricter national regulations where

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

according to Regulation (EC) No. 1907/2006

Catalogue No. 1.2290

Product name Iron(II) sulfate heptahydrate cryst., EMPROVE® ESSENTIAL Ph

Eur, BP, USP, FCC

For this product a chemical safety assessment was not carried out.

SECTION 16. Other information

Full text of H-Statements referred to under sections 2 and 3.

H302 Harmful if swallowed.H315 Causes skin irritation.

H319 Causes serious eye irritation.

Training advice

Provide adequate information, instruction and training for operators.

Labelling

Hazard pictograms



Signal word

Warning

Hazard statements

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Precautionary statements

Response

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing.

P313 Get medical advice/ attention.

according to Regulation (EC) No. 1907/2006

Catalogue No. 1.2290

Product name Iron(II) sulfate heptahydrate cryst., EMPROVE® ESSENTIAL Ph

Eur,BP,USP,FCC

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.