

according to Regulation (EC) No. 1907/2006

Revision Date 17.04.2014

Version 20.3

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

1.1 Product identifier

Catalogue No. 100563

Product name ortho-Phosphoric acid 85% suitable for use as excipient EMPROVE®

exp Ph Eur, BP, JPE, NF, E 338

REACH Registration Number This product is a mixture. REACH Registration Number see section 3.

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.merck-chemicals.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 EQ-RS * e-mail: prodsafe@merckgroup.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)

Skin corrosion, Category 1B, H314 Corrosive to metals, Category 1, H290

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

Classification (67/548/EEC or 1999/45/EC)

C Corrosive R34

For the full text of the R-phrases mentioned in this Section, see Section 16.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word
Danger

Hazard statements

H314 Causes severe skin burns and eye damage.

H290 May be corrosive to metals.

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Precautionary statements

Prevention

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response

P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P309 IF exposed or if you feel unwell:

P310 Immediately call a POISON CENTER or doctor/ physician.

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

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Reduced labelling (≤125 ml)

Hazard pictograms



Signal word
Danger

Hazard statements

H314 Causes severe skin burns and eye damage.

Precautionary statements

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.3 Other hazards

None known.

SECTION 3. Composition/information on ingredients

Chemical nature Aqueous solution

3.1 Substance not applicable

3.2 Mixture

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

Chemical Name (Concentration)

CAS-No. Registration number Classification

phosphoric acid *(>= 50 % - <= 100 %)* 7664-38-2 01-2119485924-24-

XXXX Corrosive to metals, Category 1, H290 Skin corrosion, Category 1B, H314

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

Hazardous components (1999/45/EC)

Chemical Name (Concentration)
CAS-No. Classification

according to Regulation (EC) No. 1907/2006

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For the full text of the R-phrases mentioned in this Section, see Section 16.

SECTION 4. First aid measures

4.1 Description of first aid measures

General advice

First aider needs to protect himself.

After inhalation: fresh air. Call in physician.

After skin contact: wash off with plenty of water. Remove contaminated clothing. Call a physician immediately.

After eye contact: rinse out with plenty of water. Immediately call in ophthalmologist.

After swallowing: make victim drink water (two glasses at most), avoid vomiting (risk of perforation). Call a physician immediately. Do not attempt to neutralise.

4.2 Most important symptoms and effects, both acute and delayed

Irritation and corrosion, Cough, Shortness of breath, Pain, Spasm, shock, conjunctivitis Risk of blindness!

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:

Oxides of phosphorus

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: Do not breathe vapours, aerosols. 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.

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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 with liquid-absorbent and neutralising material (e.g. Chemizorb® H⁺, Merck Art. No. 101595). Dispose of properly. Clean up affected area.

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

Requirements for storage areas and containers

No metal or light-weight-metal containers.

Storage conditions

Tightly closed.

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

Tightly fitting safety goggles

Hand protection

full contact:

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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).

Other protective equipment

Acid-resistant protective clothing

Respiratory protection

required when vapours/aerosols are generated.

Recommended Filter type: Filter P 2 (acc. to DIN 3181) for solid and liquid particles of harmful 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.

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 liquid

Colour colourless

Odour odourless

Odour Threshold not applicable

pH < 0,5

at 100 g/l 20 °C

Melting point ca. 21 °C

Boiling point/boiling range ca. 158 °C

at 1.013 hPa

Flash point does not flash

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Evaporation rate No information available.

Flammability (solid, gas) No information available.

Lower explosion limit not applicable

Upper explosion limit not applicable

Vapour pressure 2 hPa

at 20 °C

Relative vapour density No information available.

Density 1,71 g/cm³

at 20 °C

Relative density No information available.

Water solubility at 20 °C

soluble

Partition coefficient: n-

octanol/water

No information available.

Auto-ignition temperature No information available.

Decomposition temperature No information available.

Viscosity, dynamic No information available.

Explosive properties Not classified as explosive.

Oxidizing properties Oxidising potential

9.2 Other data

Ignition temperature not combustible

Viscosity, kinematic 30,5 mm²/s

at 20 °C

Corrosion May be corrosive to metals.

SECTION 10. Stability and reactivity

10.1 Reactivity

See section 10.3

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Risk of ignition or formation of inflammable gases or vapours with:

Metals, metal alloys

Possible formation of:

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Hydrogen

Violent reactions possible with:

bases, metallic oxides

10.4 Conditions to avoid

no information available

10.5 Incompatible materials

Aluminium, iron/iron-containing compounds, Mild steel

Gives off hydrogen by reaction with metals.

10.6 Hazardous decomposition products

in the event of fire: See section 5.

SECTION 11. Toxicological information

11.1 Information on toxicological effects

Mixture

Acute oral toxicity

Symptoms: If ingested, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach., Pain

Acute inhalation toxicity

Symptoms: mucosal irritations, Cough, Shortness of breath, Possible damages:, damage of respiratory tract

Acute dermal toxicity

This information is not available.

Skin irritation

Mixture causes burns.

Eye irritation

conjunctivitis Mixture causes serious eye damage. Risk of blindness!

Sensitisation

This information is not available.

Germ cell mutagenicity

This information is not available.

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:

according to Regulation (EC) No. 1907/2006

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Convulsions, shock

Handle in accordance with good industrial hygiene and safety practice.

Components

phosphoric acid

Acute oral toxicity

LD50 rat: 1.530 mg/kg (IUCLID) (Regulation (EC) No 1272/2008, Annex VI)

Acute inhalation toxicity

LC50 rat: > 0,85 mg/l; 1 h (RTECS)

Acute dermal toxicity

LD50 rabbit: 2.740 mg/kg (IUCLID)

Skin irritation

rabbit

Result: Causes burns.

(IUCLID)

Eye irritation

rabbit

Result: Causes burns.

(IUCLID)

Sensitisation

Patch test: human

Result: negative

(IUCLID)

Germ cell mutagenicity

Genotoxicity in vitro

Ames test

Result: negative

(IUCLID)

SECTION 12. Ecological information

Mixture

12.1 Toxicity

No information available.

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

Substance(s) in the mixture do(es) not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII, or a PBT/vPvB assessment was not conducted.

12.6 Other adverse effects

Additional ecological information

Harmful effect due to pH shift. Caustic even in diluted form. Depending on the concentration, phosphorus compounds may contribute to the eutrophication of water supplies.

Discharge into the environment must be avoided.

Components

phosphoric acid

according to Regulation (EC) No. 1907/2006

Catalogue No. 100563

Product name ortho-Phosphoric acid 85% suitable for use as excipient EMPROVE® exp Ph

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Toxicity to fish

LC50 Gambusia affinis (Mosquito fish): 138 mg/l; 96 h (External MSDS)

Toxicity to bacteria

EC50 activated sludge: 270 mg/l(IUCLID)

Biodegradability

Does not cause biological oxygen deficit.

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 UN number UN 1805

14.2 Proper shipping name PHOSPHORIC ACID, SOLUTION

14.3 Class814.4 Packing groupIII14.5 Environmentally hazardous--

14.6 Special precautions for yes

user

Tunnel restriction code E

Inland waterway transport (ADN)

Not relevant

Air transport (IATA)

14.1 UN number UN 1805

14.2 Proper shipping name PHOSPHORIC ACID, SOLUTION

14.3 Class814.4 Packing groupIII14.5 Environmentally hazardous--

14.6 Special precautions for no

user

Sea transport (IMDG)

14.1 UN number UN 1805

14.2 Proper shipping name PHOSPHORIC ACID SOLUTION

14.3 Class814.4 Packing groupIII14.5 Environmentally hazardous--14.6 Special precautions foryes

user

EmS F-A S-B

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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 96/82/EC

Legislation Directive 96/82/EC does not apply

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

work.

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

Regulation (EC) No 689/2008 concerning the export not regulated

and import of dangerous chemicals

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 ≥ 0.1 % (w/w).

National legislation

Storage class 8B

15.2 Chemical Safety Assessment

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.

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage.

Full text of R-phrases referred to under sections 2 and 3

R34 Causes burns.

Training advice

Provide adequate information, instruction and training for operators.

Labelling (67/548/EEC or 1999/45/EC)

Symbol(s) C Corrosive

R-phrase(s) 34 Causes burns.

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S-phrase(s) 26-36/37/39-45 In case of contact with eyes, rinse immediately with plenty of

> water and seek medical advice. Wear suitable protective clothing, gloves and eye/face protection. In case of accident or if you feel unwell, seek medical advice immediately (show

the label where possible).

Reduced labelling (≤125 ml)

Symbol(s)

Corrosive

R-phrase(s)

34

Causes burns.

26-36/37/39-45 S-phrase(s)

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable protective clothing, gloves and eye/face protection. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

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.