

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 28.08.2018

Version 16.1

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

1.1 Product identifier

Catalogue No.	100243
Product name	Citric acid monohydrate powder EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP,E 330,FCC
REACH Registration Number	01-2119457026-42-XXXX
CAS-No.	5949-29-1

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

Identified uses	Pharmaceutical production, Cosmetic raw material In compliance with the conditions described in the annex to this safety data sheet.
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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 number	Please contact the regional company representation in your country.
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SECTION 2. Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Eye irritation, Category 2, H319

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

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2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word

Warning

Hazard statements

H319 Causes serious eye irritation.

Precautionary statements

Response

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

CAS-No. 5949-29-1

2.3 Other hazards

None known.

SECTION 3. Composition/information on ingredients

3.1 Substance

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Product name	Citric acid monohydrate powder EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP,E 330,FCC

Formula	$C_6H_8O_7 \cdot H_2O$ (Hill)
EC-No.	201-069-1
Molar mass	210,14 g/mol

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

Chemical name (Concentration)

CAS-No.	Registration number	Classification
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Citric acid monohydrate ($\geq 80\%$ - $\leq 100\%$)

5949-29-1	01-2119457026-42-XXXX	Eye irritation, Category 2, H319
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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.

4.2 Most important symptoms and effects, both acute and delayed

irritant effects, pain, Bloody vomiting

4.3 Indication of any immediate medical attention and special treatment needed

No information available.

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SECTION 5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water, Carbon dioxide (CO₂), Foam, Dry powder

Unsuitable extinguishing media

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

5.2 Special hazards arising from the substance or mixture

Combustible.

Risk of dust explosion.

Vapours are heavier than air and may spread along floors.

Forms explosive mixtures with air on intense heating.

Development of hazardous combustion gases or vapours possible in the event of fire.

5.3 Advice for firefighters

Special protective equipment for firefighters

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

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

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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

Requirements for storage areas and containers

No metal containers.

Storage conditions

Tightly closed. Dry.

Recommended storage temperature see product label.

7.3 Specific end use(s)

See exposure scenario in the Annex to this MSDS.

SECTION 8. Exposure controls/personal protection

8.1 Control parameters

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Product name	Citric acid monohydrate powder EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP,E 330,FCC

Predicted No Effect Concentration (PNEC)

PNEC Fresh water	0,44 mg/l
PNEC Marine water	0,044 mg/l
PNEC Sewage treatment plant	1000 mg/l
PNEC Fresh water sediment	34,6 mg/kg
PNEC Marine sediment	3,46 mg/kg
PNEC Soil	33,1 mg/kg

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
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Product name	Citric acid monohydrate powder EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP,E 330,FCC

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

protective clothing

Respiratory protection

required when dusts are generated.

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

The entrepreneur 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	crystalline
Colour	white

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Product name	Citric acid monohydrate powder EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP,E 330,FCC

Odour	odourless
Odour Threshold	Not applicable
pH	1,85 at 50 g/l 25 °C
Melting point/range	135 - 152 °C
Boiling point/boiling range	(decomposition)
Flash point	173,9 °C Method: closed cup
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	No information available.
Upper explosion limit	No information available.
Vapour pressure	< 1 Pa at 25 °C (anhydrous substance)
Relative vapour density	No information available.
Density	1,54 g/cm ³ at 20 °C
Relative density	No information available.

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Water solubility	ca.880 g/l at 20 °C
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Partition coefficient: n-octanol/water	log Pow: -1,72 (20 °C) OECD Test Guideline 117 (anhydrous substance) Bioaccumulation is not expected.
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Auto-ignition temperature	No information available.
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Decomposition temperature	> 170 °C
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Viscosity, dynamic	No information available.
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Explosive properties	Not classified as explosive.
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Oxidizing properties	none
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9.2 Other data

Bulk density	ca.800 - 1.000 kg/m3
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SECTION 10. Stability and reactivity

10.1 Reactivity

Risk of dust explosion.

Forms explosive mixtures with air on intense heating.

A range from approx. 15 Kelvin below the flash point is to be rated as critical.

10.2 Chemical stability

releases water of crystallisation when heated.

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

10.3 Possibility of hazardous reactions

Violent reactions possible with:

Metals, Oxidizing agents, Bases, Reducing agents

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10.4 Conditions to avoid

Temperatures above melting point.
Strong heating.

10.5 Incompatible materials

Metals

10.6 Hazardous decomposition products

no information available

SECTION 11. Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity

LD50 Rat: 11.700 mg/kg
OECD Test Guideline 401

(anhydrous substance)

Symptoms: In high doses:, Irritation of mucous membranes, Pain, Bloody vomiting

Acute inhalation toxicity

Symptoms: Possible damages:, Irritation symptoms in the respiratory tract.

Acute dermal toxicity

LD50 Rat: > 2.000 mg/kg
OECD Test Guideline 402

(anhydrous substance)

Skin irritation

Rabbit

Result: No irritation

OECD Test Guideline 404

(anhydrous substance)

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Product name	Citric acid monohydrate powder EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP,E 330,FCC

Eye irritation

Rabbit

Result: Severe irritations

OECD Test Guideline 405

(anhydrous substance)

Causes serious eye irritation.

Sensitisation

This information is not available.

Germ cell mutagenicity

Genotoxicity in vivo

Chromosome aberration test

Rat

male

Oral

Bone marrow

Result: negative

Method: OECD Test Guideline 475

(anhydrous substance)

Genotoxicity in vitro

Ames test

Salmonella typhimurium

Result: negative

Method: OECD Test Guideline 471

(anhydrous substance)

Carcinogenicity

This information is not available.

Reproductive toxicity

No impairment of reproductive performance in animal experiments. (Lit.)

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Teratogenicity

Did not show teratogenic effects in animal experiments. (Lit.)

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

Substance which occurs in the human body under physiological conditions.

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 *Leuciscus idus* (Golden orfe): 440 - 760 mg/l; 96 h

(anhydrous substance) (IUCRID)

Toxicity to daphnia and other aquatic invertebrates

EC50 *E.sulcatum*: 485 mg/l; 72 h

(anhydrous substance) (maximum permissible toxic concentration) (Lit.)

EC50 *Daphnia magna* (Water flea): ca. 120 mg/l; 72 h

(anhydrous substance) (IUCRID)

Toxicity to algae

IC50 *M.aeruginosa*: 80 mg/l; 8 d

(anhydrous substance) (maximum permissible toxic concentration) (Lit.)

Toxicity to bacteria

EC50 *Pseudomonas putida*: > 10.000 mg/l; 16 h

(anhydrous substance) (Lit.)

12.2 Persistence and degradability

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Biodegradability

98 %; 2 d

OECD Test Guideline 302B

(anhydrous substance)

Readily eliminated from water

Biochemical Oxygen Demand (BOD)

481 mg/g (5 d)

(External MSDS)

Chemical Oxygen Demand (COD)

685 mg/g

(External MSDS)

Theoretical oxygen demand (ThOD)

686 mg/g

(Lit.)

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water

log Pow: -1,72 (20 °C)

OECD Test Guideline 117

(anhydrous substance) Bioaccumulation is not expected.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

12.6 Other adverse effects

Additional ecological information

Harmful effect due to pH shift.

Discharge into the environment must be avoided.

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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.
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Inland waterway transport (ADN)

Not relevant

Air transport (IATA)

14.1 - 14.6	Not classified as dangerous in the meaning of transport regulations.
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Sea transport (IMDG)

14.1 - 14.6	Not classified as dangerous in the meaning of transport regulations.
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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	SEVESO III
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Legislation	Not applicable
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Occupational restrictions	Take note of Dir 94/33/EC on the protection of young people at work.
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Regulation (EC) No 1005/2009 on substances that deplete the ozone layer not regulated

Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC not regulated

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.

SECTION 16. Other information

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

H319 Causes serious eye irritation.

Training advice

Provide adequate information, instruction and training for operators.

Labelling

Hazard pictograms



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Signal word

Warning

Hazard statements

H319 Causes serious eye irritation.

Precautionary statements

Response

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

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.

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EXPOSURE SCENARIO 1 (Industrial use)

1. Industrial use Pharmaceutical production, Cosmetic raw material)

Sectors of end-use

SU 3 Industrial uses: Uses of substances as such or in preparations at industrial sites
SU 10 Formulation [mixing] of preparations and/ or re-packaging (excluding alloys)

Chemical product category

PC19 Intermediate
PC39 Cosmetics, personal care products

Process categories

PROC1 Use in closed process, no likelihood of exposure
PROC2 Use in closed, continuous process with occasional controlled exposure
PROC3 Use in closed batch process (synthesis or formulation)
PROC4 Use in batch and other process (synthesis) where opportunity for exposure arises
PROC5 Mixing or blending in batch processes for formulation of preparations and articles (multistage and/ or significant contact)
PROC8a Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at non-dedicated facilities
PROC8b Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at dedicated facilities
PROC9 Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
PROC10 Roller application or brushing
PROC14 Production of preparations or articles by tableting, compression, extrusion, pelletisation
PROC15 Use as laboratory reagent

Environmental Release Categories

ERC2 Formulation of preparations
ERC4 Industrial use of processing aids in processes and products, not becoming part of articles
ERC6a Industrial use resulting in manufacture of another substance (use of intermediates)

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ERC6b Industrial use of reactive processing aids

2. Contributing scenarios: Operational conditions and risk management measures

2.1 Contributing scenario controlling worker exposure for: PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC10, PROC14, PROC15

Product characteristics

Concentration of the Substance in Mixture/Article	Covers the percentage of the substance in the product up to 100 %.
Physical Form (at time of use)	Solid, high dustiness

Frequency and duration of use

Frequency of use	8 hours/day
Frequency of use	5 days/week

Other operational conditions affecting workers exposure

Outdoor / Indoor	Indoor with local exhaust ventilation (LEV)
Remarks	Handle substance within a predominantly closed system provided with extract ventilation., Handle in a fume cupboard or under extract ventilation.

Technical conditions and measures

Dust must be extracted directly at the point of origin.

Organisational measures to prevent /limit releases, dispersion and exposure

Covers daily exposures up to 8 hours.

Conditions and measures related to personal protection, hygiene and health evaluation

Wear suitable gloves tested to EN374. Tightly fitting safety goggles In case of inadequate ventilation wear respiratory protection.

Additional good practice advice beyond the REACH Chemical Safety Assessment

Additional good practice advice	Wear suitable coveralls to prevent exposure to the skin.
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3. Exposure estimation and reference to its source

The life science business of Merck operates as MilliporeSigma in the US and Canada

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Product name Citric acid monohydrate powder EMPROVE® ESSENTIAL Ph
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Environment

A chemical safety assessment was performed according REACH Article 14(3), Annex I, sections 3 (Environmental Hazard Assessment) and 4 (PBT/vPvB Assessment). As no hazard was identified, an exposure assessment and risk characterisation is not necessary (REACH Annex I section 5.0).

Workers

CS	Use descriptor	Exposure duration, route, effect	RCR	Exposure Assessment Method
2.1	PROC1	longterm, combined, systemic	< 1	Qualitative assessment used to conclude safe use.
2.1	PROC2	longterm, combined, systemic	< 1	Qualitative assessment used to conclude safe use.
2.1	PROC3	longterm, combined, systemic	< 1	Qualitative assessment used to conclude safe use.
2.1	PROC4	longterm, combined, systemic	< 1	Qualitative assessment used to conclude safe use.
2.1	PROC5	longterm, combined, systemic	< 1	Qualitative assessment used to conclude safe use.
2.1	PROC8a	longterm, combined, systemic	< 1	Qualitative assessment used to conclude safe use.
2.1	PROC8b	longterm, combined, systemic	< 1	Qualitative assessment used to conclude safe use.
2.1	PROC9	longterm, combined, systemic	< 1	Qualitative assessment used to conclude safe use.
2.1	PROC10	longterm, combined, systemic	< 1	Qualitative assessment used to conclude safe use.
2.1	PROC14	longterm, combined, systemic	< 1	Qualitative assessment used to conclude safe use.
2.1	PROC15	longterm, combined, systemic	< 1	Qualitative assessment used to conclude safe use.

For (other) local effects risk management measures are based on qualitative risk characterisation.

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Product name	Citric acid monohydrate powder EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP,E 330,FCC

4. Guidance to Downstream User to evaluate whether he works inside the boundaries set by the Exposure Scenario

Please refer to the following documents: ECHA Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system; ECHA Guidance for downstream users; ECHA Guidance on information requirements and chemical safety assessment Part D: Exposure Scenario Building, Part E: Risk Characterisation and Part G: Extending the SDS; VCI/Cefic REACH Practical Guides on Exposure Assessment and Communications in the Supply Chain; CEFIC Guidance Specific Environmental Release Categories (SPERCs).

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EXPOSURE SCENARIO 2 (Professional use)

1. Professional use Pharmaceutical production, Cosmetic raw material)

Sectors of end-use

SU 22 Professional uses: Public domain (administration, education, entertainment, services, craftsmen)

Chemical product category

PC39 Cosmetics, personal care products

Environmental Release Categories

ERC8a Wide dispersive indoor use of processing aids in open systems

ERC8d Wide dispersive outdoor use of processing aids in open systems

2. Contributing scenarios: Operational conditions and risk management measures

2.1 Contributing scenario controlling worker exposure for: PROC15

Product characteristics

Concentration of the Substance in Mixture/Article	Covers the percentage of the substance in the product up to 100 %.
Physical Form (at time of use)	Solid, high dustiness

Frequency and duration of use

Frequency of use	8 hours/day
Frequency of use	5 days/week

Other operational conditions affecting workers exposure

Outdoor / Indoor	Indoor with local exhaust ventilation (LEV)
Remarks	Handle substance within a predominantly closed system provided with extract ventilation., Handle in a fume cupboard or under extract ventilation.

Technical conditions and measures

Dust must be extracted directly at the point of origin.

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Catalogue No.	100243
Product name	Citric acid monohydrate powder EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP,E 330,FCC

Organisational measures to prevent /limit releases, dispersion and exposure

Covers daily exposures up to 8 hours.

Conditions and measures related to personal protection, hygiene and health evaluation

Wear suitable gloves tested to EN374. Tightly fitting safety goggles In case of inadequate ventilation wear respiratory protection.

Additional good practice advice beyond the REACH Chemical Safety Assessment

Additional good practice advice	Wear suitable coveralls to prevent exposure to the skin.
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3. Exposure estimation and reference to its source

Environment

A chemical safety assessment was performed according REACH Article 14(3), Annex I, sections 3 (Environmental Hazard Assessment) and 4 (PBT/vPvB Assessment). As no hazard was identified, an exposure assessment and risk characterisation is not necessary (REACH Annex I section 5.0).

Workers

CS	Use descriptor	Exposure duration, route, effect	RCR	Exposure Assessment Method
2.1	PROC15	longterm, combined, systemic	< 1	Qualitative assessment used to conclude safe use.

For (other) local effects risk management measures are based on qualitative risk characterisation.

4. Guidance to Downstream User to evaluate whether he works inside the boundaries set by the Exposure Scenario

Please refer to the following documents: ECHA Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system; ECHA Guidance for downstream users; ECHA Guidance on information requirements and chemical safety assessment Part D: Exposure Scenario Building, Part E: Risk Characterisation and Part G: Extending the SDS; VCI/Cefic REACH Practical Guides on Exposure Assessment and Communications in the Supply Chain; CEFIC Guidance Specific Environmental Release Categories (SPERCs).

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EXPOSURE SCENARIO 3 (Consumer use)

1. Consumer use Pharmaceutical production, Cosmetic raw material)

Sectors of end-use

SU 21 Consumer uses: Private households (= general public = consumers)

Chemical product category

PC39 Cosmetics, personal care products

Environmental Release Categories

ERC8a Wide dispersive indoor use of processing aids in open systems

ERC8d Wide dispersive outdoor use of processing aids in open systems

2. Contributing scenarios: Operational conditions and risk management measures

3. Exposure estimation and reference to its source

Environment

A chemical safety assessment was performed according REACH Article 14(3), Annex I, sections 3 (Environmental Hazard Assessment) and 4 (PBT/vPvB Assessment). As no hazard was identified, an exposure assessment and risk characterisation is not necessary (REACH Annex I section 5.0).

In accordance with REACH Article 14(5b), exposure estimations and risk characterizations for human health do not need to be performed for uses of substances in cosmetic products which are under the scope of Directive 76/768/EEC.

4. Guidance to Downstream User to evaluate whether he works inside the boundaries set by the Exposure Scenario

Please refer to the following documents: ECHA Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system; ECHA Guidance for downstream users; ECHA Guidance on information requirements and chemical safety assessment Part D: Exposure Scenario Building, Part E: Risk Characterisation and Part G: Extending the SDS; VCI/Cefic REACH

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Practical Guides on Exposure Assessment and Communications in the Supply Chain; CEFIC
Guidance Specific Environmental Release Categories (SPERCs).