

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version 8.3
Revision Date 01.07.2021
Print Date 30.09.2021

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

1.1 Product identifiers

Product name : Citric acid anhydrous powder EMPROVE®
EXPERT Ph Eur,BP,JP,USP,ACS

Product Number : 1.37002
Catalogue No. : 137002
Brand : Millipore
REACH No. : 01-2119457026-42-XXXX
CAS-No. : 77-92-9

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

Identified uses : Pharmaceutical production, Reagent for analysis

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Chemie GmbH
Eschenstrasse 5
D-82024 TAUFKIRCHEN
Telephone : +49 (0)89 6513-1130
Fax : +49 (0)89 6513-1161
E-mail address : technischerservice@merckgroup.com

1.4 Emergency telephone

Emergency Phone # : 0800 181 7059 (CHEMTREC Deutschland)
+49 (0)696 43508409 (CHEMTREC
weltweit)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to 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.

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008

Pictogram




Signal word

Warning

Hazard statement(s) H319	Causes serious eye irritation.
Precautionary statement(s) P264 P280 P305 + P351 + P338	Wash skin thoroughly after handling. Wear eye protection/ face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313	If eye irritation persists: Get medical advice/ attention.
Supplemental Hazard Statements	none

Reduced Labeling (<= 125 ml)

Pictogram	
Signal word	Warning
Hazard statement(s)	none
Precautionary statement(s)	none
Supplemental Hazard Statements	none

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.1 Substances

Formula	:	C6H8O7
Molecular weight	:	192,12 g/mol
CAS-No.	:	77-92-9
EC-No.	:	201-069-1

Component	Classification	Concentration
citric acid		
CAS-No.	77-92-9	Eye Irrit. 2; H319
EC-No.	201-069-1	
		<= 100 %

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

SECTION 4: First aid measures

4.1 Description of first-aid measures

General advice

Show this material safety data sheet to the doctor in attendance.

If inhaled

After inhalation: fresh air.

In case of skin contact

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower.

In case of eye contact

After eye contact: rinse out with plenty of water. Call in ophthalmologist. Remove contact lenses.

If swallowed

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

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures**5.1 Extinguishing media****Suitable extinguishing media**

Water Foam Carbon dioxide (CO₂) 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

Carbon oxides

Combustible.

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

Risk of dust explosion.

5.3 Advice for firefighters

In the event of fire, wear self-contained breathing apparatus.

5.4 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.

For personal protection 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

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

No metal containers.

Tightly closed. Dry.

Recommended storage temperature see product label.

Storage class

Storage class (TRGS 510): 13: Non Combustible Solids

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

Ingredients with workplace control parameters

Component	CAS-No.	Value	Control parameters	Basis
citric acid	77-92-9	AGW	2 mg/m ³	Germany. TRGS 900 - Occupational exposure limit values.
	Remarks	When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child		
Remarks	No data available			

8.2 Exposure controls

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

Skin protection

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).

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested:KCL 741 Dermatril® L

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).

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested: KCL 741 Dermatril® L

Body Protection

protective clothing

Respiratory protection

required when dusts are generated.

Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system.

Recommended Filter type: Filter type P2

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.

Control of environmental exposure

Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- | | |
|-------------------------------------------------|------------------------------------------------------------|
| a) Appearance | Form: solid
Color: colorless |
| b) Odor | odorless |
| c) Odor Threshold | Not applicable |
| d) pH | ca.1,7 at 100 g/l at 20 °C |
| e) Melting point/freezing point | Melting point: ca.153 °C |
| f) Initial boiling point and boiling range | 200 °C at 1.013 hPa - (decomposition) |
| g) Flash point | Not applicable |
| h) Evaporation rate | No data available |
| i) Flammability (solid, gas) | The product is not flammable. |
| j) Upper/lower flammability or explosive limits | No data available |
| k) Vapor pressure | < 0,1 hPa at 25 °C |
| l) Vapor density | No data available |
| m) Relative density | 1,67 at 20 °C |
| n) Water solubility | 1.330 g/l at 20 °C |
| o) Partition coefficient: | log Pow: -1,72 at 20 °C - Bioaccumulation is not expected. |

- n-octanol/water
- p) Autoignition temperature No data available
- q) Decomposition temperature No data available
- r) Viscosity Viscosity, kinematic: No data available
Viscosity, dynamic: No data available
- s) Explosive properties No data available
- t) Oxidizing properties No data available

9.2 Other safety information

- Bulk density ca.560 kg/m³
- Dissociation constant 3,13 at 25 °C

SECTION 10: Stability and reactivity

10.1 Reactivity

The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

10.2 Chemical stability

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

10.4 Conditions to avoid

no information available

10.5 Incompatible materials

Metals

10.6 Hazardous decomposition products

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - Rat - male - 11.700 mg/kg
(OECD Test Guideline 401)
Inhalation: No data available

LD50 Dermal - Rat - male and female - > 2.000 mg/kg
(OECD Test Guideline 402)

Skin corrosion/irritation

Skin - Rabbit

Result: No skin irritation - 4 h
(OECD Test Guideline 404)

Serious eye damage/eye irritation

Eyes - Rabbit

Result: Severe irritations
(OECD Test Guideline 405)

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

Test Type: Ames test

Test system: Salmonella typhimurium

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 471

Result: negative

Test Type: Chromosome aberration test

Species: Rat

Cell type: Bone marrow

Application Route: Oral

Method: OECD Test Guideline 475

Result: negative

Carcinogenicity

No data available

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

11.2 Additional Information

Repeated dose toxicity - Rat - male and female - Oral - 10 d - NOAEL (No observed adverse effect level) - 4.000 mg/kg

Remarks: (ECHA)

Vomiting, Diarrhea, Damage to tooth enamel., Dermatitis

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish

LC50 - Leuciscus idus (Golden orfe) - 440 - 760 mg/l - 96 h

Remarks: (IUCLID)

Toxicity to daphnia and other aquatic invertebrates EC5 - E.sulcatum - 485 mg/l - 72 h
Remarks: (Lit.)

EC50 - Daphnia magna (Water flea) - ca. 120 mg/l - 72 h
Remarks: (IUCLID)

Toxicity to algae IC5 - Scenedesmus quadricauda (Green algae) - 640 mg/l - 7 d
Remarks: (maximum permissible toxic concentration) (Lit.)

Toxicity to bacteria EC5 - Pseudomonas putida - > 10.000 mg/l - 16 h
Remarks: (maximum permissible toxic concentration) (Lit.)

12.2 Persistence and degradability

Biodegradability aerobic - Exposure time 28 d
Result: 97 % - Readily biodegradable.
(OECD Test Guideline 301B)

Biochemical Oxygen Demand (BOD) 526 mg/g
Remarks: (IUCLID)

Chemical Oxygen Demand (COD) 728 mg/g
Remarks: (IUCLID)

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Harmful effect due to pH shift.
Discharge into the environment must be avoided.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Waste material must be disposed of in accordance with the national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself. See www.retrologistik.com for processes regarding the return of chemicals and containers, or contact us there if you have further questions. Notice Directive on waste 2008/98/EC.

SECTION 14: Transport information

14.1 UN number

ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4 Packaging group

ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

Further information

Not classified as dangerous in the meaning of transport regulations.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

Water contaminating class (Germany):

WGK 1, slightly water endangering - ID-Number 57Classification according to AwSV, Annex 1 (4)

Other regulations

Take note of Dir 94/33/EC on the protection of young people at work.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has been carried out for this substance.

SECTION 16: Other information

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

H319 Causes serious eye irritation.

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

Copyright 2020 Sigma-Aldrich Co. LLC. License granted to make unlimited paper copies for internal use only.

The branding on the header and/or footer of this document may temporarily not visually match the product purchased as we transition our branding. However, all of the information in the document regarding the product remains unchanged and matches the product ordered. For further information please contact mlsbranding@sial.com.

Annex: Exposure scenario

Identified uses:

Use: Industrial use

SU 3: Industrial uses: Uses of substances as such or in preparations at industrial sites
SU 3, SU9, SU 10: Industrial uses: Uses of substances as such or in preparations at industrial sites, Manufacture of fine chemicals, Formulation [mixing] of preparations and/ or re-packaging (excluding alloys)
PC19: Intermediate PC21: Laboratory chemicals PC39: Cosmetics, personal care products
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, pelletization PROC15: Use as laboratory reagent
ERC2, ERC4, ERC6a, ERC6b: Formulation of preparations, Industrial use of processing aids in processes and products, not becoming part of articles, Industrial use resulting in manufacture of another substance (use of intermediates), Industrial use of reactive processing aids

Use: Professional use

SU 22: Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
SU 22: Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
PC21: Laboratory chemicals PC39: Cosmetics, personal care products
PROC15: Use as laboratory reagent
ERC2, ERC8a, ERC8d: Formulation of preparations, Wide dispersive indoor use of processing aids in open systems, Wide dispersive outdoor use of processing aids in open systems

Use: Consumer use

SU 21: Consumer uses: Private households (= general public = consumers)
SU 21: Consumer uses: Private households (= general public = consumers)
PC39: Cosmetics, personal care products
ERC8a, ERC8d: Wide dispersive indoor use of processing aids in open systems, Wide dispersive outdoor use of processing aids in open systems

1. Short title of Exposure Scenario: Industrial use

Main User Groups	: SU 3
Sectors of end-use	: SU 3, SU9, SU 10
Chemical product category	: PC19, PC21, PC39
Process categories	: PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC10, PROC14, PROC15
Environmental Release Categories	: ERC2, ERC4, ERC6a, ERC6b:

2.2 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 % (unless stated differently).
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)
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.

Organizational 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

Wear suitable coveralls to prevent exposure to the skin.

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

Contributing Scenario	Exposure Assessment Method	Specific conditions	Value	Level of Exposure	RCR*
PROC1	Qualitative assessment used to conclude safe use.	longterm, combined, systemic			< 1
PROC2	Qualitative assessment used to conclude safe use.	longterm, combined, systemic			< 1
PROC3	Qualitative assessment used to conclude safe use.	longterm, combined, systemic			< 1
PROC4	Qualitative assessment used to conclude safe use.	longterm, combined, systemic			< 1
PROC5	Qualitative assessment used to conclude safe use.	longterm, combined, systemic			< 1
PROC8a	Qualitative assessment used to conclude safe use.	longterm, combined, systemic			< 1
PROC8b	Qualitative assessment used to conclude safe use.	longterm, combined, systemic			< 1
PROC9	Qualitative assessment used to conclude safe use.	longterm, combined, systemic			< 1
PROC10	Qualitative assessment used to conclude safe use.	longterm, combined, systemic			< 1
PROC14	Qualitative assessment used to conclude safe use.	longterm, combined, systemic			< 1

PROC15	Qualitative assessment used to conclude safe use.	longterm, combined, systemic			< 1
--------	---------------------------------------------------	------------------------------	--	--	-----

*Risk characterisation ratio

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).

1. Short title of Exposure Scenario: Professional use

Main User Groups : **SU 22**
 Sectors of end-use : **SU 22**
 Chemical product category : **PC21, PC39**
 Process categories : **PROC15**
 Environmental Release Categories : **ERC2, ERC8a, ERC8d:**

2.2 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 % (unless stated differently).
 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)
 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.

Organizational 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

Wear suitable coveralls to prevent exposure to the skin.

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

Contributing Scenario	Exposure Assessment Method	Specific conditions	Value	Level of Exposure	RCR*
PROC15	Qualitative assessment used to conclude safe use.	longterm, combined, systemic			< 1

*Risk characterisation ratio

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).

1. Short title of Exposure Scenario: Consumer use

Main User Groups : **SU 21**
Sectors of end-use : **SU 21**
Chemical product category : **PC39**
Environmental Release Categories : **ERC8a, ERC8d:**

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).

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).