



# MATERIAL SAFETY DATA SHEET

according to the (US) Hazard Communication Standard (29 CFR 1910.1200)

Revision Date 08/13/2013

Version 1.1

## SECTION 1. Identification

### Product identifier

Product number	100242
Product code	100242
Product name	Citric acid monohydrate cryst., suitable for use as excipient EMPROVE® exp Ph Eur,BP,JP,USP,E 330,FCC

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

Identified uses	Pharmaceutical production, Cosmetic raw material
-----------------	--

### Details of the supplier of the safety data sheet

Company	EMD Millipore Corporation   290 Concord Road, Billerica, MA 01821, United States of America   SDS Phone Support: +1-978-715-1335   General Inquiries: +1-978-715-4321   Monday to Friday, 9:00 AM to 4:00 PM Eastern Time (GMT-5)
---------	--

Emergency telephone	800-424-9300 CHEMTREC (USA) +1-703-527-3887 CHEMTREC (International) 24 Hours/day; 7 Days/week
---------------------	--

## SECTION 2. Hazards identification

### GHS Classification

Eye irritation, Category 2, H319

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

### GHS-Labeling

#### *Hazard pictograms*



#### *Signal Word*

Warning

#### *Hazard Statements*

H319 Causes serious eye irritation.

#### *Precautionary Statements*

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

# MATERIAL SAFETY DATA SHEET

according to the (US) Hazard Communication Standard (29 CFR 1910.1200)

Product number	100242	Version 1.1
Product name	Citric acid monohydrate cryst., suitable for use as excipient EMPROVE® exp Ph Eur,BP,JP,USP,E 330,FCC	

---

## OSHA Hazards

This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

## Other hazards

None known.

---

## SECTION 3. Composition/information on ingredients

Formula	$C_6H_8O_7 \cdot H_2O$ (Hill)
CAS-No.	5949-29-1
Molar mass	210.14 g/mol

## Hazardous ingredients

*Chemical Name ( Concentration)*

CAS-No.

*Citric acid monohydrate (  $\geq 90\%$  -  $\leq 100\%$  )*

5949-29-1

---

## SECTION 4. First aid measures

### Description of first-aid measures

*Inhalation*

After inhalation: fresh air.

*Skin contact*

After skin contact: wash off with plenty of water. Remove contaminated clothing.

*Eye contact*

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

*Ingestion*

After swallowing: make victim drink water (two glasses at most). Consult doctor if feeling unwell.

Never give anything by mouth to an unconscious person.

### Most important symptoms and effects, both acute and delayed

irritant effects, pain, Bloody vomiting

### Indication of any immediate medical attention and special treatment needed

No information available.

---

## SECTION 5. Fire-fighting measures

### Extinguishing media

*Suitable extinguishing media*

Water, Carbon dioxide (CO<sub>2</sub>), Foam, Dry powder

*Unsuitable extinguishing media*

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

### Special hazards arising from the substance or mixture

---

## MATERIAL SAFETY DATA SHEET

according to the (US) Hazard Communication Standard (29 CFR 1910.1200)

Product number	100242	Version 1.1
Product name	Citric acid monohydrate cryst., suitable for use as excipient EMPROVE® exp Ph Eur,BP,JP,USP,E 330,FCC	

---

Combustible.

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

### Advice for firefighters

*Special protective equipment for fire-fighters*

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

### Personal precautions, protective equipment and emergency procedures

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

Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

Advice for emergency responders: Protective equipment see section 8.

### Environmental precautions

Do not empty into drains.

### 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.

---

## SECTION 7. Handling and storage

### Precautions for safe handling

Observe label precautions.

### Conditions for safe storage, including any incompatibilities

*Requirements for storage areas and containers*

No metal containers.

Tightly closed. Dry.

Storage temperature: no restrictions.

---

## SECTION 8. Exposure controls/personal protection

### Exposure limit(s)

Contains no substances with occupational exposure limit values.

### Engineering measures

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

### Individual protection measures

Protective clothing should be selected specifically for the workplace, depending on concentration and quantity of the hazardous substances handled. The chemical resistance of the protective equipment should be inquired at the respective supplier.

---

## MATERIAL SAFETY DATA SHEET

according to the (US) Hazard Communication Standard (29 CFR 1910.1200)

Product number	100242	Version 1.1
Product name	Citric acid monohydrate cryst., suitable for use as excipient EMPROVE® exp Ph Eur,BP,JP,USP,E 330,FCC	

---

### *Hygiene measures*

Immediately change contaminated clothing. Apply skin- protective barrier cream. Wash hands and face after working with substance.

### *Eye/face protection*

Safety glasses

### *Hand protection*

Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

### *Other protective equipment:*

protective clothing

### *Respiratory protection*

required when dusts are generated.

Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

---

## SECTION 9. Physical and chemical properties

Physical state	solid
Color	white
Odor	odorless
Odor Threshold	not applicable
pH	No information available.
Melting point	135 - 152 °C
Boiling point/boiling range	(decomposition)
Flash point	not applicable
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	115,000 mg/m <sup>3</sup>
Upper explosion limit	No information available.
Vapor pressure	< 0.1 hPa at 68 °F ( 20 °C) (anhydrous substance)
Relative vapor density	No information available.

## MATERIAL SAFETY DATA SHEET

according to the (US) Hazard Communication Standard (29 CFR 1910.1200)

Product number	100242	Version 1.1
Product name	Citric acid monohydrate cryst., suitable for use as excipient EMPROVE® exp Ph Eur,BP,JP,USP,E 330,FCC	

---

Relative density	1.54 g/cm <sup>3</sup> at 68 °F ( 20 °C)
Water solubility	ca. 1,630 g/l at 68 °F ( 20 °C)
Partition coefficient: n-octanol/water	log Pow: -1.72 ( 20 °C) OECD Test Guideline 117 (anhydrous substance) Bioaccumulation is not expected (log Pow <1).
Autoignition temperature	No information available.
Decomposition temperature	> 338 °F ( > 170 °C)
Viscosity, dynamic	No information available.
Explosive properties	not applicable
Ignition temperature	1004 °F ( 540 °C) (anhydrous substance)
Bulk density	ca. 800 - 1,000 kg/m <sup>3</sup>

---

### SECTION 10. Stability and reactivity

#### 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.

#### Chemical stability

releases water of crystallization when heated.

#### Possibility of hazardous reactions

Violent reactions possible with:

Metals, Oxidizing agents, Bases, Reducing agents

#### Conditions to avoid

Temperatures above melting point.

#### Incompatible materials

Metals

#### Hazardous decomposition products

no information available

## MATERIAL SAFETY DATA SHEET

according to the (US) Hazard Communication Standard (29 CFR 1910.1200)

Product number	100242	Version 1.1
Product name	Citric acid monohydrate cryst., suitable for use as excipient EMPROVE® exp Ph Eur,BP,JP,USP,E 330,FCC	

---

### SECTION 11. Toxicological information

#### Information on toxicological effects

##### *Likely route of exposure*

Eye contact, Skin contact, Ingestion

##### *Acute oral toxicity*

LD50 rat: 3,000 mg/kg (anhydrous substance) (RTECS)

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

##### *Acute inhalation toxicity*

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

##### *Skin irritation*

rabbit

Result: No irritation

OECD Test Guideline 404

(anhydrous substance)

##### *Eye irritation*

rabbit

Result: Severe irritations

OECD Test Guideline 405

(anhydrous substance)

Causes serious eye irritation.

##### *Genotoxicity in vitro*

Ames test

Result: negative

(Lit.)

##### *Reproductive toxicity*

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

##### *Teratogenicity*

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

##### *Specific target organ systemic toxicity - single exposure*

The substance or mixture is not classified as specific target organ toxicant, single exposure.

##### *Specific target organ systemic toxicity - repeated exposure*

The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

##### *Aspiration hazard*

Regarding the available data the classification criteria are not fulfilled.

#### Carcinogenicity

IARC	No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
------	--

OSHA	No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential
------	--

## MATERIAL SAFETY DATA SHEET

according to the (US) Hazard Communication Standard (29 CFR 1910.1200)

Product number	100242	Version 1.1
Product name	Citric acid monohydrate cryst., suitable for use as excipient EMPROVE® exp Ph Eur,BP,JP,USP,E 330,FCC	

---

NTP	carcinogen by OSHA. No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
ACGIH	No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

### 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

### Ecotoxicity

#### *Toxicity to fish*

LC50 *Leuciscus idus* (Golden orfe): 440 - 760 mg/l; 96 h (anhydrous substance) (IUCLID)

#### *Toxicity to daphnia and other aquatic invertebrates*

EC5 *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) (IUCLID)

#### *Toxicity to algae*

IC5 *M.aeruginosa*: 80 mg/l; 8 d (anhydrous substance) (maximum permissible toxic concentration) (Lit.)

#### *Toxicity to bacteria*

EC5 *Pseudomonas putida*: > 10,000 mg/l; 16 h (anhydrous substance) (Lit.)

### Persistence and degradability

#### *Biodegradability*

98 %; 2 d

OECD Test Guideline 302B

(anhydrous substance)

Easily eliminable.

#### *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.)

### Bioaccumulative potential

## MATERIAL SAFETY DATA SHEET

according to the (US) Hazard Communication Standard (29 CFR 1910.1200)

Product number	100242	Version 1.1
Product name	Citric acid monohydrate cryst., suitable for use as excipient EMPROVE® exp Ph Eur,BP,JP,USP,E 330,FCC	

---

*Partition coefficient: n-octanol/water*

log Pow: -1.72 ( 20 °C)

OECD Test Guideline 117

(anhydrous substance) Bioaccumulation is not expected (log Pow <1).

### **Mobility in soil**

No information available.

*Additional ecological information*

Harmful effect due to pH shift.

Discharge into the environment must be avoided.

---

## **SECTION 13. Disposal considerations**

The information presented only applies to the material as supplied. The identification based on characteristic(s) or listing may not apply if the material has been used or otherwise contaminated. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable regulations. Disposal should be in accordance with applicable regional, national and local laws and regulations.

---

## **SECTION 14. Transport information**

### **Land transport (DOT)**

Not classified as dangerous in the meaning of transport regulations.

### **Air transport (IATA)**

Not classified as dangerous in the meaning of transport regulations.

### **Sea transport (IMDG)**

Not classified as dangerous in the meaning of transport regulations.

---

## **SECTION 15. Regulatory information**

### **United States of America**

#### **OSHA Hazards**

Eye irritant

This information is based on 29 CFR 1910.1200 criteria prior to adoption of the GHS, and may deviate from the GHS information on the label and in section 2.

#### **SARA 311/312 Hazards**

Acute Health Hazard

#### **SARA 313**

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

#### **SARA 302**

SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.



## MATERIAL SAFETY DATA SHEET

according to the (US) Hazard Communication Standard (29 CFR 1910.1200)

Product number	100242	Version 1.1
Product name	Citric acid monohydrate cryst., suitable for use as excipient EMPROVE® exp Ph Eur,BP,JP,USP,E 330,FCC	

---

### Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

### DEA List I

Not listed

### DEA List II

Not listed

## US State Regulations

### Massachusetts Right To Know

Remarks

No components are subject to the Massachusetts Right to Know Act.

### Pennsylvania Right To Know

*Ingredients*

Citric acid monohydrate

### New Jersey Right To Know

*Ingredients*

Citric acid monohydrate

### California Prop 65 Components

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

### Notification status

TSCA: All components of the product are listed in the TSCA-inventory.

DSL: All components of this product are on the Canadian DSL.

---

## SECTION 16. Other information

### Training advice

Provide adequate information, instruction and training for operators.

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

H319 Causes serious eye irritation.

### 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](http://www.wikipedia.org).

# MATERIAL SAFETY DATA SHEET

according to the (US) Hazard Communication Standard (29 CFR 1910.1200)

Product number	100242	Version 1.1
Product name	Citric acid monohydrate cryst., suitable for use as excipient EMPROVE® exp Ph Eur,BP,JP,USP,E 330,FCC	

---

Revision Date 08/13/2013

---

The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to appropriate safety precautions. It does not represent a warranty of any product properties and we assume no liability for any loss or injury which may result from the use of this information. Users should conduct their own investigations to determine the suitability of the information.

***All rights reserved. Millipore and the "M" Mark are registered trademarks of Merck KGaA, Darmstadt, Germany.***