

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version 8.10

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GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

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

### 1.1 Product identifiers

Product name : Silicon dioxide colloidal, highly dispersed  
EMPROVE® ESSENTIAL Ph Eur,NF,JP,E 551

Product Number : 1.13126  
Catalogue No. : 113126  
Brand : Millipore  
REACH No. : 01-2119379499-16-XXXX  
CAS-No. : 7631-86-9

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

Identified uses : Pharmaceutical production

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

Company : Merck Life Science S.r.l.  
Via Monte Rosa 93  
I-20149 MILANO

Telephone : +39 02 3341 7340  
Fax : +39 02 3801 0737  
E-mail address : serviziotecnico@merckgroup.com

### 1.4 Emergency telephone

Emergency Phone # : 800-789-767 (CHEMTREC Italia)  
+39-02-4555-7031 (CHEMTREC chiamate internazionali)  
+39 02-6610-1029 (Centro Antiveleni Niguarda Ca' Granda - Milano)

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

### 2.2 Label elements

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.



### 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.

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## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Formula	: SiO <sub>2</sub>
Molecular weight	: 60,08 g/mol
CAS-No.	: 7631-86-9
EC-No.	: 231-545-4

No components need to be disclosed according to the applicable regulations.

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## SECTION 4: First aid measures

### 4.1 Description of first-aid measures

#### 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. Remove contact lenses.

#### If swallowed

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

### 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

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## 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

silicon oxides

Not combustible.

Ambient fire may liberate hazardous vapours.



### 5.3 Advice for firefighters

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

### 5.4 Further information

Suppress (knock down) gases/vapors/mists with a water spray jet.

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## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid inhalation of dusts. Evacuate the danger area, observe emergency procedures, consult an expert.

For personal protection see section 8.

### 6.2 Environmental precautions

No special precautionary measures necessary.

### 6.3 Methods and materials for containment and cleaning up

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.

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## 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

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

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## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Ingredients with workplace control parameters

### 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](http://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](http://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

### **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 P1

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**

No special precautionary measures necessary.

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## **SECTION 9: Physical and chemical properties**

### **9.1 Information on basic physical and chemical properties**

- |   |                                  |
|---|----------------------------------|
| a) Physical state                               | solid                            |
| b) Color  | white                            |
| c) Odor   | odorless                         |
| d) Melting point/freezing point                 | Melting point: 1.713 °C - (ECHA) |
| e) Initial boiling point and boiling range      | 2.230 °C                         |
| f) Flammability (solid, gas)                    | The product is not flammable.    |
| g) Upper/lower flammability or explosive limits | No data available                |
| h) Flash point                                  | Not applicable                   |
| i) Autoignition                                 | does not ignite                  |



	temperature	
j)	Decomposition temperature	No data available
k)	pH	3,7 - 4,7 at $\geq 40$ g/l at 25 °C
l)	Viscosity	Viscosity, kinematic: No data available Viscosity, dynamic: No data available
m)	Water solubility	ca.0,076 g/l at 37 °C - OECD Test Guideline 105- slightly soluble
n)	Partition coefficient: n-octanol/water	Not applicable for inorganic substances
o)	Vapor pressure	No data available
p)	Density	2,56 g/cm <sup>3</sup>
	Relative density	No data available
q)	Relative vapor density	No data available
r)	Particle characteristics	No data available
s)	Explosive properties	No data available
t)	Oxidizing properties	none

## 9.2 Other safety information

Bulk density	ca.200 - 1.430 kg/m <sup>3</sup>
Particle size	< 0,5 mm - Particle size

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No data available

### 10.2 Chemical stability

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

### 10.3 Possibility of hazardous reactions

Exothermic reaction with:

Hydrogen halides  
halogen oxides  
alkali hydroxides  
sodium  
xenon hexafluoride

### 10.4 Conditions to avoid

no information available

### 10.5 Incompatible materials

No data available



## 10.6 Hazardous decomposition products

In the event of fire: see section 5

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Acute toxicity

LD50 Oral - Rat - male and female - > 5.000 mg/kg

(OECD Test Guideline 401)

LC50 Inhalation - Rat - male and female - 4 h - > 5,01 mg/l - aerosol

(OECD Test Guideline 436)

LD50 Dermal - Rabbit - > 5.000 mg/kg

Remarks: (ECHA)

#### Skin corrosion/irritation

Skin - Rabbit

Result: No skin irritation - 4 h

(OECD Test Guideline 404)

#### Serious eye damage/eye irritation

Eyes - Rabbit

Result: No eye irritation - 24 h

(OECD Test Guideline 405)

#### Respiratory or skin sensitization

in vivo assay - Guinea pig

Result: Not a skin sensitizer.

(OECD Test Guideline 406)

#### 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: In vitro mammalian cell gene mutation test

Test system: Chinese hamster ovary cells

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 476

Result: negative

Test Type: Chromosome aberration test in vitro

Test system: Chinese hamster ovary cells

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 473

Result: negative

Test Type: gene mutation test

Species: Rat

Application Route: Inhalation

Result: negative

Remarks: (ECHA)



**Carcinogenicity**

This product is or contains a component that is not classifiable as to its carcinogenicity based on its IARC, ACGIH, NTP, or EPA classification.

**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****Endocrine disrupting properties****Product:**

Assessment

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

This is a generally physiologically inert substance that displays no hazardous properties after oral intake and skin contact and after inhalation of its dusts as long as the total dust limit for silicic acid is adhered to. Intensive contact with the eye may lead to irritation symptoms.

Handle in accordance with good industrial hygiene and safety practice.

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**SECTION 12: Ecological information****12.1 Toxicity**

Toxicity to fish	static test LC50 - Pimephales promelas (fathead minnow) - > 5.000 mg/l - 96 h (OECD Test Guideline 203)
Toxicity to daphnia and other aquatic invertebrates	static test EC50 - Daphnia magna (Water flea) - > 5.000 mg/l (OECD Test Guideline 202)
Toxicity to algae	static test ErC50 - Desmodesmus subspicatus (green algae) - > 173,1 mg/l (OECD Test Guideline 201)
Toxicity to bacteria	static test EC50 - activated sludge - > 1.000 mg/l - 3 h (OECD Test Guideline 209)

**12.2 Persistence and degradability**

The methods for determining biodegradability are not applicable to inorganic substances.







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## **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.

### **15.2 Chemical Safety Assessment**

For this product a chemical safety assessment was not carried out

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## **SECTION 16: Other information**

### **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](http://www.sigma-aldrich.com) and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

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