

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 01.06.2017

Version 14.0

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

### 1.1 Product identifier

Catalogue No.	100366
Product name	(S)-Lactic acid about 90% suitable for use as excipient EMPROVE® exp Ph Eur,BP,E 270

REACH Registration Number	This product is a mixture. REACH Registration Number see section 3. This product is a mixture. REACH Registration Number see section 3.
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### 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 ( <a href="http://www.merckgroup.com">www.merckgroup.com</a> ).
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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: <a href="mailto:prodsafe@merckgroup.com">prodsafe@merckgroup.com</a>

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)

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Skin irritation, Category 2, H315

Serious eye damage, Category 1, H318

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

## 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

*Hazard pictograms*



*Signal word*

Danger

*Hazard statements*

H315 Causes skin irritation.

H318 Causes serious eye damage.

*Precautionary statements*

Prevention

P280 Wear eye protection.

Response

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

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

P313 Get medical advice/ attention.

**Reduced labelling (≤125 ml)**

*Hazard pictograms*



*Signal word*

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Danger

*Hazard statements*

H318 Causes serious eye damage.

*Precautionary statements*

P280 Wear eye protection.

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

P313 Get medical advice/ attention.

## 2.3 Other hazards

None known.

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## SECTION 3. Composition/information on ingredients

### 3.1 Substance

Not applicable

### 3.2 Mixture

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

*Chemical name (Concentration)*

CAS-No.	Registration number	Classification
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lactic acid ( $\geq 50\%$ - $\leq 100\%$ )		
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79-33-4	*)	
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Skin irritation, Category 2, H315

Serious eye damage, Category 1, H318

\*) A registration number is not available for this substance as the substance or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

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

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## 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. Immediately 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

Irritation and corrosion

Risk of corneal clouding.

Risk of serious damage to eyes.

### 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, Foam, Carbon dioxide (CO<sub>2</sub>), 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.

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

### 5.3 Advice for firefighters

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## *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*

Prevent fire extinguishing water from contaminating surface water or the ground water system.

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## **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.

### **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<sup>+</sup>, Merck Art. No. 101595). Dispose of properly. Clean up affected area.

### **6.4 Reference to other sections**

Indications about waste treatment see section 13.

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## **SECTION 7. Handling and storage**

### **7.1 Precautions for safe handling**

#### *Advice on safe handling*

Observe label precautions.

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## *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**

### *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.

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## **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:

Glove material: Nitrile rubber

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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](http://www.kcl.de)).

## *Other protective equipment*

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 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.

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

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

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Form	oily
Colour	colourless
Odour	odourless
Odour Threshold	Not applicable
pH	ca. 2,8 at 10 g/l 20 °C
Melting point	18 °C
Boiling point/boiling range	122 °C at 20 hPa
Flash point	does not flash
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	Not applicable
Upper explosion limit	Not applicable
Vapour pressure	0,1 hPa at 25 °C
Relative vapour density	No information available.
Density	1,21 g/cm <sup>3</sup> at 20 °C



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Relative density	No information available.
Water solubility	at 20 °C soluble
Partition coefficient: n-octanol/water	log Pow: -0,62 OECD Test Guideline 117 (refers to pure substance) Bioaccumulation is not expected.
Auto-ignition temperature	No information available.
Decomposition temperature	No information available.
Viscosity, dynamic	20 - 40 mPa.s at 20 °C
Explosive properties	Not classified as explosive.
Oxidizing properties	none

## 9.2 Other data

Ignition temperature	not combustible
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## 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

Violent reactions possible with:

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Oxidizing agents, bases

## 10.4 Conditions to avoid

Strong heating.

## 10.5 Incompatible materials

no information available

## 10.6 Hazardous decomposition products

no information available

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## SECTION 11. Toxicological information

### 11.1 Information on toxicological effects

#### Mixture

##### *Acute oral toxicity*

Symptoms: Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.

##### *Acute inhalation toxicity*

Symptoms: Possible damages:, mucosal irritations

##### *Acute dermal toxicity*

This information is not available.

##### *Skin irritation*

Mixture causes skin irritation.

##### *Eye irritation*

Risk of corneal clouding.

Mixture causes serious eye damage.

##### *Sensitisation*

This information is not available.

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## *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

After swallowing of large amounts:

Kidney

Other dangerous properties can not be excluded.

Handle in accordance with good industrial hygiene and safety practice.

## Components

### *lactic acid*

#### *Acute oral toxicity*

LD50 Rat: 3.543 mg/kg

US-EPA

#### *Acute inhalation toxicity*

LC50 Rat: > 7,94 mg/l; 4 h ; aerosol

OECD Test Guideline 403

#### *Acute dermal toxicity*

LD50 Rabbit: > 2.000 mg/kg

US-EPA

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## *Skin irritation*

Rabbit

Result: Irritations

OECD Test Guideline 404

## *Eye irritation*

In vitro study

Result: Irreversible effects on the eye

(ECHA)

## *Sensitisation*

Buehler Test Guinea pig

Result: negative

(ECHA)

## *Germ cell mutagenicity*

### *Genotoxicity in vitro*

Ames test

Escherichia coli/Salmonella typhimurium

Result: negative

Method: OECD Test Guideline 471

Mutagenicity (mammal cell test): chromosome aberration.

Human lymphocytes

Result: negative

Method: OECD Test Guideline 473

In vitro mammalian cell gene mutation test

Mouse lymphoma test

Result: negative

Method: OECD Test Guideline 476

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## SECTION 12. Ecological information

### Mixture

#### 12.1 Toxicity

No information available.

#### 12.2 Persistence and degradability

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No information available.

## 12.3 Bioaccumulative potential

*Partition coefficient: n-octanol/water*

log Pow: -0,62

OECD Test Guideline 117

(refers to pure substance) Bioaccumulation is not expected.

## 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*

Biological effects:

Harmful effect due to pH shift.

Discharge into the environment must be avoided.

## Components

*lactic acid*

*Toxicity to fish*

static test LC50 Oncorhynchus mykiss (rainbow trout): 130 mg/l; 96 h  
US-EPA

*Toxicity to daphnia and other aquatic invertebrates*

static test EC50 Daphnia magna (Water flea): 130 mg/l; 48 h

Analytical monitoring: yes

OECD Test Guideline 202

static test NOEC Daphnia magna (Water flea): 180 mg/l; 48 h

Analytical monitoring: yes

OECD Test Guideline 202

*Toxicity to algae*

static test IC50 Pseudokirchneriella subcapitata (green algae): 3.500 mg/l; 72 h

Analytical monitoring: yes

OECD Test Guideline 201

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static test NOEC *Pseudokirchneriella subcapitata* (green algae): 1.520 mg/l; 72 h

Analytical monitoring: yes

OECD Test Guideline 201

#### *Toxicity to bacteria*

static test EC50 activated sludge: > 100 mg/l; 3 h

OECD Test Guideline 209

#### *Biodegradability*

67 %; 20 d; aerobic Biochemical oxygen demand

(ECHA)

Readily biodegradable

#### *Biochemical Oxygen Demand (BOD)*

0,45 mg/l (5 d)

Method: Tested according to Annex V of Directive 67/548/EEC.

#### *Ratio BOD/COD*

50 %

(IUCLID)

#### *Ratio COD/ThBOD*

100 %

(Lit.)

#### *Partition coefficient: n-octanol/water*

log Pow:  $\geq -0,54$  (25 °C)

OECD Test Guideline 107

#### *Surface tension*

70,7 mN/m

at 20 °C

Method: OECD Test Guideline 115

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## SECTION 13. Disposal considerations

### *Waste treatment methods*

See [www.retrologistik.com](http://www.retrologistik.com) for processes regarding the return of chemicals and containers, or contact us there if you have further questions.

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## 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

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## 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).
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## *National legislation*

Storage class 10 - 13

## 15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

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## SECTION 16. Other information

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

H315	Causes skin irritation.
H318	Causes serious eye damage.

### Training advice

Provide adequate information, instruction and training for operators.



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## Labelling

### *Hazard pictograms*



### *Signal word*

Danger

### *Hazard statements*

H315 Causes skin irritation.

H318 Causes serious eye damage.

### *Precautionary statements*

#### Prevention

P280 Wear eye protection.

#### Response

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

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

P313 Get medical advice/ attention.

## 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).

## Regional representation

This information is given on the authorised Safety Data Sheet for your country.

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*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.*