

## SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 06.02.2014

Version 3.1

**SECTION 1. Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

Catalogue No.	100967
Product name	Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP
REACH Registration Number	01-2119457610-43-XXXX
CAS-No.	64-17-5

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

Identified uses	Pharmaceutical production, Solvent, Cosmetic raw material In compliance with the conditions described in the annex to this safety data sheet.
-----------------	---

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

Responsible Department	EQ-RS * e-mail: prodsafe@merckgroup.com
Regional representation	Merck Chemicals Ltd * Boulevard Industrial Park * Padge Road * Beeston * Nottingham * NG9 2JR * Tel. 01159 430840 * information@merckchem.co.uk.

<b>1.4 Emergency telephone number</b>	+49 (0) 6151 722440
---	---------------------

**SECTION 2. Hazards identification****2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Flammable liquid, Category 2, H225

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

**Classification (67/548/EEC or 1999/45/EC)**

F Highly flammable R11

For the full text of the R-phrases mentioned in this Section, see Section 16.

**2.2 Label elements****Labelling (REGULATION (EC) No 1272/2008)***Hazard pictograms**Signal word*

Danger

*Hazard statements*

H225 Highly flammable liquid and vapour.

SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Catalogue No. 100967  
Product name Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP

---

*Precautionary statements*

Prevention

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Storage

P403 + P235 Store in a well-ventilated place. Keep cool.

**Reduced labelling (≤125 ml)**

*Hazard pictograms*



*Signal word*  
Danger

*Index-No.* 603-002-00-5

**2.3 Other hazards**

None known.

---

**SECTION 3. Composition/information on ingredients**

Chemical nature Solvent mixture

**3.1 Substance**

Formula	C <sub>2</sub> H <sub>5</sub> OH	C <sub>2</sub> H <sub>6</sub> O (Hill)
Index-No.	603-002-00-5	
EC-No.	200-578-6	
Molar mass	46.07 g/mol	

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

Remarks	No disclosure requirement according to Regulation (EC) No. 1907/2006.
---------	---

**3.2 Mixture**

not applicable

---

**SECTION 4. First aid measures**

**4.1 Description of first aid measures**

After inhalation: fresh air.

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

After eye contact: rinse out with plenty of water with the eyelid held wide open. Call in ophthalmologist if necessary.

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**

irritant effects, respiratory paralysis, Dizziness, narcosis, inebriation, euphoria, Nausea, Vomiting

---

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Catalogue No.

100967

Product name

Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP

---

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

No information available.

---

## SECTION 5. Firefighting measures

### 5.1 Extinguishing media

*Suitable extinguishing media*

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

*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.

Vapours are heavier than air and may spread along floors.

Forms explosive mixtures with air at ambient temperatures.

Pay attention to flashback.

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.

Remove container from danger zone and cool with water.

---

## SECTION 6. Accidental release measures

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

Advice for non-emergency personnel: Avoid substance contact. Do not breathe vapours, aerosols. Ensure adequate ventilation. Keep away from heat and sources of ignition. 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. Risk of explosion.

### 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 material (e.g. Chemizorb®). Dispose of properly. Clean up affected area.

### 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.

*Advice on protection against fire and explosion*

Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharge.

---

SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Catalogue No. 100967  
Product name Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP

---

*Hygiene measures*

Change contaminated clothing. Preventive skin protection recommended. Wash hands after working with substance.

**7.2 Conditions for safe storage, including any incompatibilities**

*Storage conditions*

Keep away from heat and sources of ignition. Keep container tightly closed in a dry and well-ventilated place.

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**

SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Catalogue No. 100967  
Product name Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP

**Components with workplace control parameters**

*Components*

Basis	Value	Threshold limits	Remarks
<i>ethanol (64-17-5)</i>			
EH40 WEL	Time Weighted Average (TWA):	1,000 ppm 1,920 mg/m <sup>3</sup>	

**Derived No Effect Level (DNEL)**

Worker DNEL, acute	Local effects	inhalation	1900 mg/m <sup>3</sup>
Worker DNEL, longterm	Systemic effects	dermal	343 mg/kg Body weight
Worker DNEL, longterm	Systemic effects	inhalation	950 mg/m <sup>3</sup>
Consumer DNEL, acute	Local effects	inhalation	950 mg/m <sup>3</sup>
Consumer DNEL, longterm	Systemic effects	dermal	206 mg/kg Body weight
Consumer DNEL, longterm	Systemic effects	inhalation	114 mg/m <sup>3</sup>
Consumer DNEL, longterm	Systemic effects	oral	87 mg/kg Body weight

**Recommended monitoring procedures**

Methods for measurement of the workplace atmosphere have to correspond to the requirements of norms DIN EN 482 and DIN EN 689.

**Predicted No Effect Concentration (PNEC)**

PNEC Fresh water	0.96 mg/l
PNEC Marine water	0.79 mg/l
PNEC Fresh water sediment	3.6 mg/kg
PNEC Soil	0.63 mg/kg
PNEC Aquatic intermittent release	2.75 mg/l
PNEC Sewage treatment plant	580 mg/l
PNEC oral	720 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

SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Catalogue No. 100967  
Product name Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP

---

*Hand protection*

full contact:

Glove material: butyl-rubber  
Glove thickness: 0.7 mm  
Break through time: > 480 min

splash contact:

Glove material: Nitrile rubber  
Glove thickness: 0.40 mm  
Break through time: > 120 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 898 Butoject® (full contact), KCL 730 Camatril® -Velours (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*

Flame retardant antistatic protective clothing

*Respiratory protection*

required when vapours/aerosols are generated.

Empfohlener Filtertyp: Filter A (acc. to DIN 3181) for vapours of organic compounds

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.

Risk of explosion.

---

**SECTION 9. Physical and chemical properties**

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

Form	liquid
Colour	colourless
Odour	alcohol-like
Odour Threshold	0.1 - 5058.5 ppm
pH	7.0 at 10 g/l 20 °C
Melting point	-117 °C
Boiling point/boiling range	78 °C at 1,013 hPa

SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Catalogue No. 100967  
Product name Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP

---

Flash point	17 °C
Evaporation rate	No information available.
Flammability (solid, gas)	not applicable
Lower explosion limit	3.5 %(V)
Upper explosion limit	15 %(V)
Vapour pressure	ca.59 hPa at 20 °C
Relative vapour density	No information available.
Relative density	0.805 - 0.812 g/cm <sup>3</sup> at 20 °C
Water solubility	at 20 °C soluble
Partition coefficient: n-octanol/water	log Pow: -0.31 (experimental) (Lit.) Bioaccumulation is not expected.
Auto-ignition temperature	No information available.
Decomposition temperature	Distillable in an undecomposed state at normal pressure.
Viscosity, dynamic	1.2 mPa.s at 20 °C
Explosive properties	Not classified as explosive.
Oxidizing properties	none

## 9.2 Other data

Ignition temperature	425 °C
----------------------	--------

---

## SECTION 10. Stability and reactivity

### 10.1 Reactivity

Vapours may form explosive mixture with air.

### 10.2 Chemical stability

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

### 10.3 Possibility of hazardous reactions

Risk of explosion/exothermic reaction with:

hydrogen peroxide, perchlorates, perchloric acid, Nitric acid, mercury(II) nitrate, permanganic acid, Nitriles, peroxi compounds, Strong oxidizing agents, nitrosyl compounds, Peroxides, sodium, Potassium, halogen oxides, calcium hypochlorite, nitrogen dioxide, metallic oxides, uranium hexafluoride, iodides, Chlorine, Alkali metals, Alkaline earth metals, alkali oxides, Ethylene oxide silver, with, Nitric acid

SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Catalogue No. 100967  
Product name Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP

---

silver compounds, with, Ammonia  
potassium permanganate, with, conc. sulfuric acid  
Risk of ignition or formation of inflammable gases or vapours with:  
halogen-halogen compounds, chromium(VI) oxide, chromyl chloride, Fluorine, hydrides, Oxides of phosphorus, platinum  
Nitric acid, with, potassium permanganate

#### 10.4 Conditions to avoid

Warming.

#### 10.5 Incompatible materials

rubber, various plastics

#### 10.6 Hazardous decomposition products

no information available

---

### SECTION 11. Toxicological information

#### 11.1 Information on toxicological effects

##### *Acute oral toxicity*

LD50 rat: 6,200 mg/kg (IUCLID)

Symptoms: Nausea, Vomiting

##### *Acute inhalation toxicity*

LC50 rat: 95.6 mg/l; 4 h (RTECS)

absorption

Symptoms: slight mucosal irritations

##### *Acute dermal toxicity*

This information is not available.

##### *Skin irritation*

rabbit

Result: No irritation

OECD Test Guideline 404

Repeated or prolonged exposure may cause skin irritation and dermatitis, due to degreasing properties of the product.

##### *Eye irritation*

This information is not available.

##### *Sensitisation*

Sensitisation test (Magnusson and Kligman):

Result: negative

(IUCLID)

##### *Germ cell mutagenicity*

##### *Genotoxicity in vitro*

Ames test

Salmonella typhimurium

Result: negative

(National Toxicology Program)

##### *Carcinogenicity*

This information is not available.

##### *Reproductive toxicity*

This information is not available.



SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Catalogue No. 100967  
Product name Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP

---

*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

Systemic effects:

euphoria

After absorption of large quantities:

Dizziness, inebriation, narcosis, respiratory paralysis

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): 8,140 mg/l; 48 h (IUCLID)

*Toxicity to daphnia and other aquatic invertebrates*

EC5 *E.sulcatum*: 65 mg/l; 72 h (Lit.)

EC50 *Daphnia magna* (Water flea): 9,268 - 14,221 mg/l; 48 h (IUCLID)

*Toxicity to algae*

IC5 *Scenedesmus quadricauda* (Green algae): 5,000 mg/l; 7 d (Lit.)

*Toxicity to bacteria*

EC5 *Pseudomonas putida*: 6,500 mg/l; 16 h (IUCLID)

### 12.2 Persistence and degradability

*Biodegradability*

94 %

OECD Test Guideline 301E

Readily biodegradable.

*Biochemical Oxygen Demand (BOD)*

930 - 1,670 mg/g (5 d)

(Lit.)

*Theoretical oxygen demand (ThOD)*

2,100 mg/g

(Lit.)

*Ratio COD/ThBOD*

90 %

(Lit.)

### 12.3 Bioaccumulative potential

*Partition coefficient: n-octanol/water*

log Pow: -0.31

(experimental)

(Lit.) Bioaccumulation is not expected.

### 12.4 Mobility in soil

No information available.

### 12.5 Results of PBT and vPvB assessment

SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Catalogue No. 100967  
Product name Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP

---

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*

No interference with wastewater treatment plants are to be expected when used properly.  
Discharge into the environment must be avoided.

---

### SECTION 13. Disposal considerations

#### *Waste treatment methods*

Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other 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](http://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 UN number	UN 1170
14.2 Proper shipping name	ETHANOL
14.3 Class	3
14.4 Packing group	II
14.5 Environmentally hazardous	--
14.6 Special precautions for user	yes
Tunnel restriction code	D/E

#### Inland waterway transport (ADN)

Not relevant

#### Air transport (IATA)

14.1 UN number	UN 1170
14.2 Proper shipping name	ETHANOL
14.3 Class	3
14.4 Packing group	II
14.5 Environmentally hazardous	--
14.6 Special precautions for user	no

#### Sea transport (IMDG)

14.1 UN number	UN 1170
14.2 Proper shipping name	ETHANOL
14.3 Class	3
14.4 Packing group	II
14.5 Environmentally hazardous	--
14.6 Special precautions for user	yes
EmS	F-E S-D

SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Catalogue No. 100967  
Product name Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP

---

**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 96/82/EC  
Legislation Highly flammable  
7b  
Quantity 1: 5,000 t  
Quantity 2: 50,000 t

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

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

Regulation (EC) No 689/2008 concerning the export and import of dangerous chemicals 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 3

**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.**

H225 Highly flammable liquid and vapour.

**Full text of R-phrases referred to under sections 2 and 3**

R11 Highly flammable.

**Training advice**

Provide adequate information, instruction and training for operators.

**Labelling (67/548/EEC or 1999/45/EC)**

Symbol(s)  F Highly flammable

SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Catalogue No. 100967  
Product name Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP

---

*R*-phrase(s) 11 Highly flammable.  
*S*-phrase(s) 7-16 Keep container tightly closed. Keep away from sources of  
ignition - No smoking.

EC-No. 200-578-6 EC Label

**Reduced labelling (≤125 ml)**

Symbol(s)  F Highly flammable

**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).

---

*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.*

SAFETY DATA SHEET – Annex  
according to Regulation (EC) No. 1907/2006

Catalogue No. 100967  
Product name Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP

---

**EXPOSURE SCENARIO 1 (Industrial use)**

---

**1. Industrial use (Pharmaceutical production, Solvent, Cosmetic raw material)**

**Sectors of end-use**

*SU 3* Industrial uses: Uses of substances as such or in preparations at industrial sites  
*SU 9* Manufacture of fine chemicals  
*SU 10* Formulation [mixing] of preparations and/ or re-packaging (excluding alloys)

**Chemical product category**

*PC19* Intermediate  
*PC21* Laboratory chemicals  
*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**

*ERC1* Manufacture of substances  
*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)

---

**2. Contributing scenarios: Operational conditions and risk management measures**

**2.1 Contributing scenario controlling environmental exposure for: ERC1, ERC4, ERC6a**

**Amount used**

Annual amount per site 400000 t

**Environment factors not influenced by risk management**

Flow rate 18,000 m<sup>3</sup>/d

**Other given operational conditions affecting environmental exposure**

Number of emission days per year 350  
Emission or Release Factor: Air 70 %  
Emission or Release Factor: Water 87 %

**Conditions and measures related to municipal sewage treatment plant**

Type of Sewage Treatment Plant Municipal sewage treatment plant

---

SAFETY DATA SHEET – Annex  
according to Regulation (EC) No. 1907/2006

Catalogue No. 100967  
Product name Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP

---

Effectiveness (of a measure) 90 %

---

## 2.2 Contributing scenario controlling environmental exposure for: ERC2

### Amount used

Annual amount per site 75000 t

### Environment factors not influenced by risk management

Flow rate 18,000 m<sup>3</sup>/d

### Other given operational conditions affecting environmental exposure

Number of emission days per year 300

### Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant Municipal sewage treatment plant

Effectiveness (of a measure) 90 %

---

## 2.3 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) High volatile liquid

### Frequency and duration of use

Frequency of use 8 hours/day

### Other operational conditions affecting workers exposure

Outdoor / Indoor Indoor without local exhaust ventilation (LEV)

### Additional good practice advice beyond the REACH Chemical Safety Assessment

Additional good practice advice Wear suitable gloves (tested to EN374) and eye protection.

---

## 3. Exposure estimation and reference to its source

SAFETY DATA SHEET – Annex  
according to Regulation (EC) No. 1907/2006

Catalogue No. 100967  
Product name Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP

**Environment**

CS	Use descriptor	Msafe	Compartment	RCR	Exposure Assessment Method
2.1	ERC1		Fresh water	< 0.01	ECETOC TRA
			Marine water	< 0.01	ECETOC TRA
			Soil	< 0.01	ECETOC TRA
2.1	ERC4		Fresh water	< 0.01	ECETOC TRA
			Marine water	< 0.01	ECETOC TRA
			Soil	< 0.01	ECETOC TRA
2.1	ERC6a		Fresh water	< 0.01	ECETOC TRA
			Marine water	< 0.01	ECETOC TRA
			Soil	< 0.01	ECETOC TRA
2.2	ERC2		Fresh water	0.11	ECETOC TRA
			Marine water	0.01	ECETOC TRA
			Soil	< 0.01	ECETOC TRA

**Workers**

CS	Use descriptor	Exposure duration, route, effect	RCR	Exposure Assessment Method
2.3	PROC1	longterm, inhalative, systemic	< 0.01	ECETOC TRA 3
		longterm, dermal, systemic	< 0.01	ECETOC TRA 3
		longterm, combined, systemic	< 0.01	
2.3	PROC2	longterm, inhalative, systemic	0.05	ECETOC TRA 3
		longterm, dermal, systemic	< 0.01	ECETOC TRA 3
		longterm, combined, systemic	0.05	
2.3	PROC3	longterm, inhalative, systemic	0.10	ECETOC TRA 3
		longterm, dermal, systemic	< 0.01	ECETOC TRA 3
		longterm, combined, systemic	0.10	
2.3	PROC4	longterm, inhalative, systemic	0.20	ECETOC TRA 3
		longterm, dermal, systemic	0.02	ECETOC TRA 3
		longterm, combined, systemic	0.22	
2.3	PROC5	longterm, inhalative, systemic	0.50	ECETOC TRA 3
		longterm, dermal, systemic	0.04	ECETOC TRA 3
		longterm, combined, systemic	0.54	
2.3	PROC8a	longterm, inhalative, systemic	0.50	ECETOC TRA 3
		longterm, dermal, systemic	0.04	ECETOC TRA 3
		longterm, combined, systemic	0.54	
2.3	PROC8b	longterm, inhalative, systemic	0.30	ECETOC TRA 3
		longterm, dermal, systemic	0.04	ECETOC TRA 3
		longterm, combined, systemic	0.34	
2.3	PROC9	longterm, inhalative, systemic	0.40	ECETOC TRA 3
		longterm, dermal, systemic	0.02	ECETOC TRA 3
		longterm, combined, systemic	0.42	
2.3	PROC10	longterm, inhalative, systemic	0.50	ECETOC TRA 3
		longterm, dermal, systemic	0.08	ECETOC TRA 3
		longterm, combined, systemic	0.58	
2.3	PROC14	longterm, inhalative, systemic	0.50	ECETOC TRA 3
		longterm, dermal, systemic	0.01	ECETOC TRA 3
		longterm, combined, systemic	0.51	
2.3	PROC15	longterm, inhalative, systemic	0.10	ECETOC TRA 3
		longterm, dermal, systemic	< 0.01	ECETOC TRA 3
		longterm, combined, systemic	0.10	

SAFETY DATA SHEET – Annex  
according to Regulation (EC) No. 1907/2006

Catalogue No.	100967
Product name	Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP

---

The default parameters and -efficiencies of the applied exposure assessment model were used for the calculation (unless stated differently).

---

#### **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).

For scaling of worker exposure assessments performed with ECETOC TRA, please consult the Merck tool SciDeEx® at [www.merck-chemicals.com](http://www.merck-chemicals.com).



SAFETY DATA SHEET – Annex  
according to Regulation (EC) No. 1907/2006

Catalogue No. 100967  
Product name Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP

---

**EXPOSURE SCENARIO 2 (Professional use)**

---

**1. Professional use (Pharmaceutical production, Solvent, Cosmetic raw material)**

**Sectors of end-use**

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

**Chemical product category**

*PC21* Laboratory chemicals  
*PC39* Cosmetics, personal care products

**Process categories**

*PROC15* Use as laboratory reagent

**Environmental Release Categories**

*ERC2* Formulation of preparations  
*ERC6a* Industrial use resulting in manufacture of another substance (use of intermediates)  
*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 environmental exposure for: ERC2**

**Amount used**

Annual amount per site 75000 t

**Environment factors not influenced by risk management**

Flow rate 18,000 m<sup>3</sup>/d

**Other given operational conditions affecting environmental exposure**

Number of emission days per year 300

**Conditions and measures related to municipal sewage treatment plant**

Type of Sewage Treatment Plant Municipal sewage treatment plant  
Effectiveness (of a measure) 90 %

---

**2.2 Contributing scenario controlling environmental exposure for: ERC6a**

**Amount used**

Annual amount per site 400000 t

**Environment factors not influenced by risk management**

Flow rate 18,000 m<sup>3</sup>/d

**Other given operational conditions affecting environmental exposure**

Number of emission days per year 350  
Emission or Release Factor: Air 70 %  
Emission or Release Factor: Water 87 %

**Conditions and measures related to municipal sewage treatment plant**

Type of Sewage Treatment Plant Municipal sewage treatment plant  
Effectiveness (of a measure) 90 %

---

SAFETY DATA SHEET – Annex  
according to Regulation (EC) No. 1907/2006

Catalogue No. 100967  
Product name Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP

**2.3 Contributing scenario controlling environmental exposure for: ERC8a, ERC8d**

**Amount used**

Annual amount per site 10000 t

**Environment factors not influenced by risk management**

Flow rate 18,000 m<sup>3</sup>/d

**Other given operational conditions affecting environmental exposure**

Number of emission days per year 365

**Conditions and measures related to municipal sewage treatment plant**

Type of Sewage Treatment Plant Municipal sewage treatment plant  
Effectiveness (of a measure) 90 %

**2.4 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) High volatile liquid

**Frequency and duration of use**

Frequency of use 8 hours/day

**Other operational conditions affecting workers exposure**

Outdoor / Indoor Indoor without local exhaust ventilation (LEV)

**Additional good practice advice beyond the REACH Chemical Safety Assessment**

Additional good practice advice Wear suitable gloves (tested to EN374) and eye protection.

**3. Exposure estimation and reference to its source**

**Environment**

CS	Use descriptor	Msafe	Compartment	RCR	Exposure Assessment Method
2.1	ERC2		Fresh water	0.11	ECETOC TRA
			Marine water	0.01	ECETOC TRA
			Soil	< 0.01	ECETOC TRA
2.2	ERC6a		Fresh water	< 0.01	ECETOC TRA
			Marine water	< 0.01	ECETOC TRA
			Soil	< 0.01	ECETOC TRA
2.3	ERC8a		Fresh water	0.05	ECETOC TRA
			Marine water	0.01	ECETOC TRA
			Soil	0.01	ECETOC TRA
2.3	ERC8d		Fresh water	0.05	ECETOC TRA
			Marine water	0.01	ECETOC TRA
			Soil	0.01	ECETOC TRA

SAFETY DATA SHEET – Annex  
according to Regulation (EC) No. 1907/2006

Catalogue No. 100967  
Product name Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP

---

**Workers**

CS	Use descriptor	Exposure duration, route, effect	RCR	Exposure Assessment Method
2.4	PROC15	longterm, inhalative, systemic	0.10	ECETOC TRA 3
		longterm, dermal, systemic	< 0.01	ECETOC TRA 3
		longterm, combined, systemic	0.10	

The default parameters and -efficiencies of the applied exposure assessment model were used for the calculation (unless stated differently).

---

**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).

For scaling of worker exposure assessments performed with ECETOC TRA, please consult the Merck tool SciDeEx® at [www.merck-chemicals.com](http://www.merck-chemicals.com).

SAFETY DATA SHEET – Annex  
according to Regulation (EC) No. 1907/2006

Catalogue No. 100967  
Product name Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP

**EXPOSURE SCENARIO 3 (Consumer use)**

**1. Consumer use (Pharmaceutical production, Solvent, 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**

**2.1 Contributing scenario controlling environmental exposure for: ERC8a, ERC8d: Wide dispersive indoor use of processing aids in open systems, Wide dispersive outdoor use of processing aids in open systems**

**Amount used**

Annual amount per site 10000 t

**Environment factors not influenced by risk management**

Flow rate 18,000 m<sup>3</sup>/d

**Other given operational conditions affecting environmental exposure**

Number of emission days per year 365

**Conditions and measures related to municipal sewage treatment plant**

Type of Sewage Treatment Plant Municipal sewage treatment plant

Effectiveness (of a measure) 90 %

**3. Exposure estimation and reference to its source**

**Environment**

CS	Use descriptor	Msafe	Compartment	RCR	Exposure Assessment Method
2.1	ERC8a		Fresh water	0.05	ECETOC TRA
			Marine water	0.01	ECETOC TRA
			Soil	0.01	ECETOC TRA
2.1	ERC8d		Fresh water	0.05	ECETOC TRA
			Marine water	0.01	ECETOC TRA
			Soil	0.01	ECETOC TRA

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.

The default parameters and -efficiencies of the applied exposure assessment model were used for the calculation (unless stated differently).

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

SAFETY DATA SHEET – Annex  
according to Regulation (EC) No. 1907/2006

Catalogue No.	100967
Product name	Ethanol 96% suitable for use as excipient EMPROVE® exp Ph Eur,JP,USP

---

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).