

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

Revision Date 09/15/2014

Version 1.3

SECTION 1. Identification

Product identifier

Product number 100967

Product name Ethanol 96% suitable for use as excipient EMPROVE® exp Ph

Eur, JP, USP

Synonyms EtOH CAS-No. 64-17-5

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

Identified uses Pharmaceutical production, Solvent, 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 | 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

Flammable liquid, Category 2, H225

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

GHS-Labeling

Hazard pictograms



Signal Word
Danger

Hazard Statements

H225 Highly flammable liquid and vapor.

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

Product number 100967 Version 1.3

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

Precautionary Statements

P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

P233 Keep container tightly closed.

P240 Ground/bond container and receiving equipment.

P241 Use explosion-proof electrical/ ventilating/ lighting/ equipment.

P242 Use only non-sparking tools.

P243 Take precautionary measures against static discharge.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

P303 + P361 + P353 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing.

Rinse skin with water/ shower.

P370 + P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.

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

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. Composition/information on ingredients

Chemical nature Solvent mixture

Formula C_2H_5OH C_2H_6O (Hill)

Synonyms EtOH

Molar mass 46.07 g/mol

Hazardous ingredients

Chemical Name (Concentration)

CAS-No.

ethanol (>= 90 % - <= 100 %)

64-17-5

Exact percentages are being withheld as a trade secret.

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.

Eve contact

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

Inaestion

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

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

Product number 100967 Version 1.3

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

Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media

Carbon dioxide (CO2), Foam, Dry powder, Water

Unsuitable extinguishing media

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

Special hazards arising from the substance or mixture

Combustible.

Vapors 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 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.

Remove container from danger zone and cool with water.

SECTION 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid substance contact. Do not breathe vapors, 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.

Environmental precautions

Do not let product enter drains. Risk of explosion.

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.

SECTION 7. Handling and storage

Precautions for 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.

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

Product number 100967 Version 1.3

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

Conditions for safe storage, including any incompatibilities

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

Store at +15°C to +25°C (+59°F to +77°F).

SECTION 8. Exposure controls/personal protection

Exposure limit(s)

,		
Ingr	2011	antc
111191	cuic	,,,,,

Basis	Value	Threshold limits	Remarks	
ethanol 64-17-5				
ACGIH	Short Term Exposure Limit (STEL):	1,000 ppm		
NIOSH/GUIDE	Recommended exposure limit (REL):	1,000 ppm 1,900 mg/m³		
OSHA_TRANS	PEL:	1,000 ppm 1,900 mg/m³		
Z1A	Time Weighted Average (TWA):	1,000 ppm 1,900 mg/m³		

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.

Hygiene measures

Change contaminated clothing. Application of skin- protective barrier cream recommended. Wash hands after working with substance.

Eve/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:

Flame retardant antistatic protective clothing.

Respiratory protection

required when vapors/aerosols 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.

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

Product number 100967 Version 1.3

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

SECTION 9. Physical and chemical properties

Physical state liquid

Color colorless

Odor alcohol-like

Odor Threshold 0.1 - 5058.5 ppm

pH 7.0

at 10 g/l 68 °F (20 °C)

Melting point -117 °C

Boiling point/boiling range 172 °F (78 °C)

at 1,013 hPa

Flash point 63 °F (17 °C)

Evaporation rate No information available.

Flammability (solid, gas) Not applicable

Lower explosion limit 3.5 %(V)

Upper explosion limit 15 %(V)

Vapor pressure ca. 59 hPa

at 68 °F (20 °C)

Relative vapor density No information available.

Density 0.805 - 0.812 g/cm³

at 68 °F (20 °C)

log Pow: -0.31

Relative density No information available.

Water solubility at 68 °F (20 °C)

soluble

Partition coefficient: n-

octanol/water (experimental)

(Lit.) Bioaccumulation is not expected.

Autoignition temperature No information available.

Decomposition temperature Distillable in an undecomposed state at normal pressure.

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

Product number 100967 Version 1.3

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

Viscosity, dynamic 1.2 mPa.s

at 68 °F (20 °C)

Explosive properties Not classified as explosive.

Oxidizing properties none

Ignition temperature 797 °F (425 °C)

SECTION 10. Stability and reactivity

Reactivity

Vapors may form explosive mixture with air.

Chemical stability

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

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

silver compounds, with, Ammonia

potassium permanganate, with, conc. sulfuric acid

Risk of ignition or formation of inflammable gases or vapors with:

halogen-halogen compounds, chromium(VI) oxide, chromyl chloride, Fluorine, hydrides, Oxides of phosphorus, platinum

Nitric acid, with, potassium permanganate

Conditions to avoid

Warming.

Keep away from open flames, hot surfaces and sources of ignition.

Incompatible materials

rubber, various plastics

Hazardous decomposition products

no information available

SECTION 11. Toxicological information

Information on toxicological effects

Likely route of exposure

Inhalation, Eye contact, Skin contact

Target Organs

Eyes

Skin

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

Product number 100967 Version 1.3

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

Respiratory system Central nervous system

Liver Blood

reproductive system 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)

Symptoms: slight mucosal irritations

absorption 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.

Sensitization

Sensitization test (Magnusson and Kligman):

Result: negative

(IUCLID)

Genotoxicity in vitro

Ames test

Salmonella typhimurium

Result: negative

(National Toxicology Program)

Carcinogenicity

Carcinogen classifications of IARC, NTP, California proposition 65 for Ethanol CAS 64-17-5 apply to beverage use only. This product is NOT intended for this use.

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

carcinogen by OSHA.

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

Product number 100967 Version 1.3

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

NTP 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

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

Ecotoxicity

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)

Persistence and degradability

Biodegradability

94 %

OECD Test Guideline 301E Readily biodegradable.

readily blodegradable.

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.)

Bioaccumulative potential

Partition coefficient: n-octanol/water

log Pow: -0.31 (experimental)

(Lit.) Bioaccumulation is not expected.

Mobility in soil

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

Product number 100967 Version 1.3

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

No information available.

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

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)

UN 1170
Proper shipping name ETHANOL

Class 3
Packing group II
Environmentally hazardous ---

Air transport (IATA)

UN number UN 1170 **Proper shipping name** ETHANOL

Class 3
Packing group II
Environmentally hazardous -Special precautions for user no

Sea transport (IMDG)

UN 1170
Proper shipping name ETHANOL

Class 3
Packing group II
Environmentally hazardous -Special precautions for user yes
EmS F-E S-D

SECTION 15. Regulatory information

United States of America

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

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

Product number 100967 Version 1.3

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

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

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

ethanol

New Jersey Right To Know

Ingredients

ethanol

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.

Labeling

Hazard pictograms



Signal Word

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

Product number 100967 Version 1.3

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

Danger

Hazard Statements

H225 Highly flammable liquid and vapor.

Precautionary Statements

Prevention

P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

P240 Ground/bond container and receiving equipment.

Storage

P403 + P233 Store in a well-ventilated place. Keep container tightly closed.

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

H225 Highly flammable liquid and vapor.

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.

Revision Date 09/15/2014

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.