

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

ETHANOLUM 85% V/V DENATURUS

EN

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name:	Ethanol 85% V/V denatured Ethanolum 85% V/V denaturus Ethanol 85% V/V gedenatureerd Ethanol à 85% V/V denature Ethanol 85% vergällt
N° CAS:	64-17-5
N° EC:	200-578-6

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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1.3 Details of the supplier of the safety data sheet

Company:	MAGIS-PHARMA NV Neerlandweg 24 2610 Wilrijk Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Flam. Liq. 2	H225
Eye Irrit. 2	H319

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.

Precautionary statements:

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233	Keep container tightly closed.

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P240	Ground and bond container and receiving equipment.
P241	Use explosion-proof [electrical/ventilating/lighting/...] equipment.
P242	Use only non-sparking tools.
P243	Take action to prevent static discharges.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER or doctor / physician.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with 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.
P337+P313	If eye irritation persists: Get medical advice / attention.
P370 + P378	In case of fire: Use alcohol resistant foam, ABC powder, BC powder, carbon dioxide, water mist to extinguish.
P403 + P235	Store in well-ventilated place. Keep cool.
P501	Dispose of contents/container in accordance with regional/national regulation.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Vapors from the product are heavier than air and may concentrate on the ground, in wells, sewers and basements.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Product name:	Ethanol
IUPAC name:	Ethanol
Synonyms:	Ethyl alcohol Methylcarbinol
N° CAS:	64-17-5
N° EC:	200-578-6
Molecular Formula:	C ₂ H ₆ O
Content:	85%

Product name:	Methyl ethyl ketone
IUPAC name:	Butan-2-one
Synonyms:	Butanone Methyl acetone
N° CAS:	78-93-3
N° EC:	201-159-0
Molecular Formula:	C ₄ H ₈ O

Product name:	Denatonium benzoate
IUPAC name:	Benzyl-[2-(2,6-dimethylanilino)-2-oxoethyl]-diethylazanium;benzoate

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Synonyms:	Lidocaine benzyl benzoate Benzenemethanaminium, N-(2-((2,6-dimethylphenyl)amino)-2-oxoethyl)-N,N-diethyl-, benzoate
N° CAS:	3734-33-6
N° EC:	223-095-2
Molecular Formula:	$C_{21}H_{29}N_2O \cdot C_7H_5O_2$
Product name:	Isopropyl alcohol
IUPAC name:	Propan-2-ol
Synonyms:	2-propanol Isopropanol
N° CAS:	67-63-0
N° EC:	200-661-7
Molecular Formula:	C_3H_8O
Product name:	Water
IUPAC name:	Oxidane
Synonyms:	Distilled water Purified water Dihydrogen oxide
N° CAS:	7732-18-5
N° EC:	231-791-2
Molecular Formula:	H_2O

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation:	Provide fresh air, provide ventilation if necessary and keep the person warm. Consult a doctor if the complaints persist. If the person is unconscious, the patient should be placed lying on his/her side.
After skin contact:	Rinse with plenty of water. Remove contaminated clothing.
After eye contact:	Rinse the eye with plenty of water in the open eyelids for several minutes. Remove contact lenses. Consult an ophthalmologist.
After ingestion:	Rinse mouth and drink plenty of water. If the person is unconscious, the patient should be placed lying on his/her side.

4.2 Most important symptoms and effects, both acute and delayed

Acute: Irritating to mucous membranes through eye contact or inhalation.
Delayed: Disturbance of the inhibitory functions of the central nervous system, redness of the skin, nausea due to intake of larger amounts.

4.3 Indication of any immediate medical attention and special treatment needed

Not necessary.

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SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Alcohol resistant foam, ABC powder, BC powder, carbon dioxide, water mist.

Unsuitable extinguishing media: Water jet, alcohol unresistant foam.

5.2 Special hazards arising from the substance/mixture

Hazardous combustion products: In case of fire, toxic fumes are released (carbon monoxide and/or carbon dioxide).
Additional Hazards: Formation of explosive gas-air mixtures. Extreme heat build-up in case of larger fires.

5.3 Advice for firefighters

Surrounding fires: Use water jet to cool exposed containers in the surroundings. Prevent contaminated extinguishing water from entering the sewer system.
In case of larger fires: block the area in question. Make sure that unprotected persons are kept away from the area.

Protection against fire: Independent respiratory protective equipment, complete protective suit.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

In case of large quantities: use personal protective equipment to prevent contamination of skin, eyes and personal clothing. Remove possible sources of ignition. Do not smoke. Take measures against static discharges. Provide adequate ventilation. Use only suitable and explosion-proof tools and devices. If available, the business plans for hazard reduction and emergency plans should be taken into account.

For emergency responders

If available, the internal and external safety management plans should be taken into account.

6.2 Environmental precautions

Precautions to take with regard to spillage

In case of smaller quantities: no special measures required.

In case of larger quantities: prevent the product from entering drains, surface water or ground water.

Precautions to be taken with regard to accidental discharge or release of the substance

Observe the precautions regarding fire and explosion.

Prevent the product from entering drains, surface water or ground water.

6.3 Methods and material for containment and cleaning up

Advice regarding containment of spillage

In case of smaller quantities: absorb in liquid binding material (sand, diatomaceous earth/kieselguhr, general binder, sawdust).

In case of larger quantities: initiate a extensive procedure: block areas, cover access to drains, close the plunger valves of the floor drains.

Suitable cleaning procedures

In case of smaller quantities: no additional cleaning procedures are required.

In case of larger quantities: use water for final purification.

6.4 Reference to other sections

Personal protection: see section 8. Disposal considerations: see section 13.

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SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Use in a well-ventilated area. Take measures to prevent static electricity discharges. Do not store with incompatible materials.
Personal protection:	Avoid inhalation of vapours and direct contact with the skin, eyes and clothing.
Technical protective measures:	Not available.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Suitable materials for packaging are: plastics resistant to solvents and stainless steel 1.4301 (V2), 1.4401 (V42), iron.
Conditions for safe storage, including any incompatibilities:	Store in dry, tightly sealed and preferably well-filled containers in a sufficiently ventilated place at a temperature of +15°C to +25°C. Provide a solid floor that is resistant to solvents. Take measures to prevent static electricity discharges. Heat creates an increase in pressure, creating a risk of bursting. All equipment must be grounded. Do not store in aluminum or aluminum alloys. Do not store with incompatible materials. If larger quantities are stored, the required retention volume must be ensured.
Storage – away from:	Keep away from sources of ignition and heat.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Control parameters ethanol

Belgium:

8 hours (TWA) 1907 mg/m³, 1000 ppm

Germany:

8 hours (TWA) 960 mg/m³, 500 ppm

France:

8 hours (TWA) 1900 mg/m³, 1000 ppm

Short period (15 min) 9500 mg/m³, 5000 ppm

Ireland:

8 hours (TWA) 1900 mg/m³, 1000 ppm

Italy:

Short period (15 min) 1000 ppm

The Netherlands:

8 hours (TWA) 260 mg/m³

Short period (15 min) 1900 mg/m³

Indication: skin

Austria:

8 hours (TWA) 1900 mg/m³, 1000 ppm

Short period (15 min) 3800 mg/m³, 1900 ppm

Switzerland:

8 hours (TWA) 960 mg/m³, 500 ppm

Short period (15 min) 1920 mg/m³, 1000 ppm

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United Kingdom:

8 hours (TWA) 1920 mg/m³, 1000 ppm

DNEL

Workers short term exposure

DNEL worker (acute, inhalation - systemic): No data required

DNEL worker (acute, inhalation - local): 1 900 mg/m³

DNEL worker (acute, dermal - systemic): No data required

DNEL worker (acute, dermal - local): No data required

Workers long-term exposure

DNEL worker (long-term, inhalation - systemic): 950 mg/m³

DNEL worker (long-term, inhalation - local): No data required

DNEL worker (long-term, dermal - systemic): 343 mg/kg bw/d

DNEL worker (long-term, dermal - local): No data required

Consumer short-term exposure

DNEL general population (acute, inhalation - systemic): No data required

DNEL general population (acute, inhalation - local): 950 mg/m³

DNEL general population (acute, dermal - systemic): No data required

DNEL general population (acute, dermal - local): No data required

Consumers long-term exposure

DNEL general population (long-term, inhalation - systemic): 114 v

DNEL general population (long-term, inhalation - local): No data required

DNEL general population (long-term, oral - local): 87 mg/kg

DNEL general population (long-term, dermal - systemic): 206 mg/kg bw/d

DNEL general population (long-term, dermal - local): No data required.

PNEC

Aquatic

fresh water: PNEC aquatic (fresh water): 0.96 mg/L

salt water: PNEC aquatic (salt water): 0.79 mg/L

accidental release: PNEC aquatic (accidental release): 2.75 mg/L

wastewater treatment: PNEC microorganisms: 580 mg/L

Sedimentation

fresh water sedimentation: PNEC sediment: 3.6 mg/kg sediment dw

salt water sedimentation: PNEC salt water sediment: 2.9 mg/kg sediment dw

On the land

soil: PNEC soil: 0.63 mg/kg soil dw

In the air

biotic: PNEC air (biotic): No data required.

abiotic: PNEC air (abiotic): No data required.

Secondary poisoning

food chain: PNEC oral: 0.72 mg/kg food

8.2 Exposure controls

Appropriate engineering control

To the extent required by the determination of the exposure scenario, an efficient local exhaust system must be provided. Measures to prevent an explosion must be taken into account.

Individual protection measures

Eye/face protection: Safety protection for eyes, e.g. safety glasses (EN 166).

Skin protection: Protective clothing that is resistant to solvents.

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Hand protection: Suitable gloves in case of prolonged direct contact (breakthrough time according to EN 374 > 480 min): Butyl rubber (butyl), recommended glove thickness: 0.7 mm.

Respiratory protection: Necessary if vapours or aerosols are formed.
Use filter A. respirator (according to DIN 3181) suitable for vapours from organic compounds.

Thermal hazards: Applicable in case of fire, see section 5.

Environmental exposure control

Remove polluted air from local exhaust and waste water in accordance with environmental regulations.

EC legislation Water (76/464/EEC): not listed

Air (1999/30/EC): not listed

Risk management measures: See section 15.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	Colourless, clear liquid.
Odour:	Characteristic odour of alcohol.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	-114 °C (ethanol)
Initial boiling point:	78 °C (ethanol)
Boiling range:	Not available.
Flash point:	15 °C (ethanol)
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	2.5 – 13.5 Vol % (ethanol)
Vapour pressure:	57.3 hPa (20 °C)
Vapour density:	Not available.
Relative density:	0,84 (20 °C)
Solubility:	Not available.
Solubility in water:	Completely miscible.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	363 °C (ethanol)
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Not available.

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SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No hazardous reactions if the instructions/advice on storage and handling of the substance have been properly applied.

Not corrosive to metals.

10.2 Chemical stability

Stable under normal storage conditions. No stabilizers required.

10.3 Possibility of hazardous reactions

Exothermic reactions: Exothermic, partly violent reaction with alkali and alkaline earth metals, strong acids and oxidizing agents possible.

No spontaneous polymerization.

10.4 Conditions to avoid

Storage temperatures > 40 °C must be avoided (increase in pressure, deformation of the packaging), if applicable it must be guaranteed that the pressure is equalized.

Avoid static electricity, explosion hazard in the vicinity of product/air mixtures.

10.5 Incompatible materials

Violent reactions: Evolution of heat in reaction with alkali and alkaline earth metals, eg sodium (laboratory) with acids, eg sulfuric acid or strong oxidizing agents.

Formation of toxic decomposition products: In the event of fire, formation of carbon monoxide is possible.

Development of explosion hazard: Formation of hydrogen/ethanol/air mixtures which react with alkali and alkaline earth metals.

Water, moisture content: No dangerous reaction with water, no formation of flammable or toxic gases.

10.6 Hazardous decomposition products

During handling and storage: In case of leakage or spillage, ethanol vapors may form explosive mixtures with air.

In case of fire: See section 5

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:

Ethanol:

LD50 (oral, rat): 10 470 mg/kg

LD50 (dermal, rabbit): > 15 800 mg/kg

LC50 (inhalation (rat, 4h)): 51 mg/l

Repeated dose toxicity:

Oral: NOAEL (90 d, rat, female): 1 730 mg/kgbw /d

Dermal: No test results available

Due to the rapid evaporation in case of skin damage, dermal exposure is negligible.

A repeated relevant dermal damage can be ruled out.

Inhalation: NOAEL (20 d, rat, man): > 20 mg/L

Skin corrosion/irritation:

Not irritating (rabbit).

Non-irritating to very slightly irritating (epidemiological studies on humans).

Based on the available data, the classification criteria of one of the categories of this hazard class are not met.

Serious eye damage/irritation:

No irreversible effects on the eye (rabbit eye, OECD 405)

Irritating to eyes (rabbit eye, OECD 405)

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Respiratory/skin sensitisation:	Not sensitive on skin (mouse, man, OECD 429) Not sensitive on skin (mouse, ear swelling test) Respiratory sensitivity: no data available. Based on the available data, the classification criteria of one of the categories of this hazard class are not met.
Germ cell mutagenicity:	Based on the available data, the classification criteria of one of the categories of this hazard class are not met.
Carcinogenicity:	Based on the available data, the classification criteria of one of the categories of this hazard class are not met.
Reproductive toxicity:	Based on the available data, the classification criteria of one of the categories of this hazard class are not met.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Respiratory tract: No test data available. Existing research results of other short chain alcohols show that severe irritation of the respiratory tract is not to be expected. Mucous membranes: No test data available. Narcotic effects: No test data available. Results from human toxicity studies based on the consumption of ethanol in alcoholic beverages cannot be used to determine the narcotic effects of ethanol as a workplace chemical. Based on the available data, the classification criteria of one of the categories of this hazard class are not met.
STOT-repeated exposure:	Neurotoxicity: Based on the available data, the classification criteria of one of the categories of this hazard class are not met.
Aspiration Hazard:	No indication that the substance causes inhalation toxicity. Based on the available data, the classification criteria of one of the categories of this hazard class are not met.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Vapors may be irritating to the eyes.
Skin contact:	Not available.
Inhalation:	Exposure to vapors with a concentration of 1,000 ppm or more can cause irritation to the nose, throat and lungs.
Ingestion:	May cause nausea, vomiting, loss of coordination, central nervous system depression and unconsciousness.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic compartment and sediment (ethanol):
LC50 (fish, 96 hours) (mg/l): 11 200
EC50 (Daphnia, 48 hours) (mg/l): 5 012 (*Ceriodaphnia dubia*)
IC50 (algae, 72 hours) (mg/l): 275

12.2 Persistence and degradability

Not available.

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12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Does not meet the PBT and vPvB criteria according to Annex XIII of Regulation (EC) No. 1907/2006.

12.6 Other adverse effects

Chemical oxygen demand: COD = 1 900 mg/g

Biochemical oxygen demand: BOD5 = 1 000 mg/g

Other information: The product should not be allowed in water without pre-treatment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation: Do not dispose of waste together with household waste. Prevent waste from entering the sewage system. (Dirt) incineration is recommended. National or regional regulations must be observed.

Contaminated packaging: Uncleaned empty packaging should be handled according to the content. The labeling of uncleaned packaging should not be removed. Empty the packaging completely, use water if necessary. Drain the water used for rinsing and cleaning in accordance with local legal requirements. Uncontaminated packaging can be reused.

Damaged packaging can be recycled. Packaging that cannot be cleaned should be disposed of according to the product.

Other information: European list of waste (EURL) 07 01 04

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), 1170
IATA/ICAO (Air) :

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), ETHANOL (ETHYL ALCOHOL)
IATA/ICAO (Air) :

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), 3
IATA/ICAO (Air) :

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), II
IATA/ICAO (Air) :

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), Marine environmental pollutant: No.
IATA/ICAO (Air) :

14.6 Special precautions for user

Individual transport: In case of transport in cars: observe national regulations or guidelines.

Transportation within or outside the company premises: No additional measures required.

Dangerous good label: 3

Tunnel category: (D/E)

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Limited quantity (LQ): 1L

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not within the scope of Marpol 73/78.

14.8 Additional transport information

In the case of a trial shipment, the specific transport conditions of the service provider must be taken into account (if required).

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol:



Risk phrases:

R11 Highly flammable.
R20/22 Harmful by inhalation and if swallowed.
R36/37 Irritation to eyes and respiratory system.
R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases:

S7 Keep container tightly closed.
S16 Keep away of sources of ignition – No smoking.

15.2 Chemical safety assessment

A chemical safety assessment has been carried out for this product.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

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16.4 Method of classification in case of mixture

Classification based on the main component.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

Quality Department
MAGIS-PHARMA NV
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