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

1.1 Product identifier

Product name: Ethanol 96% bon gout

Ethanolum 96% bon gout Ethanol 96% bon gout Ethanol à 96% bon goût Ethanol 96% bon gout

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.

1.3 Details of the supplier of the safety data sheet

Company: FRAVER NV

Keizershoek 336 2550 Kontich 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. Lig. 2 H225

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.

Precautionary statements:

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.

No smoking.

P233 Keep container tightly closed.
P242 Use only non-sparking tools.

P280 Wear protective gloves/protective clothing/eye protection.

P370+P378 In case of fire: Use powder, alcohol resistant foam, plenty of water, carbon dioxide

to extinguish.

Store in a well-ventilated place. Keep cool.

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P403+P235

Dispose of contents/container in accordance with local/regional/national/inter-

P501

national regulation.

Additional applicable label

elements:

Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:

IUPAC name:

Not applicable.

Synonyms:

Not applicable.

No CAS:

Not applicable.

No EC:

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: C₂H₆O

Content: 96%

Product name : Water IUPAC name : Oxidane

Synonyms: Distilled water, Purified water, Dihydrogen oxide

 N° CAS : 7732-18-5 N° EC : 231-791-2 $Molecular\ formula: H_{2}O$

Content: 4%

SECTION 4: FIRST AID MEASURES

After inhalation:

4.1 Description of first aid measures

General notes: Remove the person in question from exposure to the substance and lay the person

down. Provide fresh air, rest and keep the person warm (with a blanket). If the person is unconscious or if the complaints persist, seek medical attention immediately. Contaminated clothing and shoes should be removed.

Exposure to vapors with a concentration of 1,000 ppm or more can cause irritation

to the nose, throat and lungs. When exposed to higher concentrations: see ingestion. Move the victim to fresh air and let rest in a comfortable position. If necessary, give mouth to mouth or artificial respiration and keep the respiratory

tract clear. Seek medical advice if necessary.

Rinse with plenty of water. Remove contaminated clothing.

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After skin contact: Vapors may be irritating to the eyes. Rinse immediately with plenty of fresh water

for at least 10 minutes, keeping the eyelids wide open. Consult an ophthalmologist

if necessary.

May cause nausea, vomiting, loss of coordination, central nervous system

depression and unconsciousness. Immediately rinse mouth and drink plenty of water, if possible with 20-40g activated charcoal (norit) in 10% suspension. Do not

administer milk or digestible oils. Aspiration while swallowing or vomiting can cause serious lung damage. Keep the respiratory tract clear and call a doctor. Give mouth to mouth or artificial respiration if necessary. After swallowing large amounts:

gastric lavage.

4.2 Most important symptoms and effects, both acute and delayed

Acute: Irritant to mucous membranes due to 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 available.

After eye contact:

After ingestion:

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water, CO₂, foam, powder. Cool containers with spray water from a

safe distance.

Not available. Unsuitable extinguishing media:

5.2 Special hazards arising from the substance/mixture

Not available.

5.3 Advice for firefighters

Use water jet to cool exposed containers in the surroundings. Surrounding fires:

> 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.

Do not stay in the hazardous area without suitable chemical Protection against fire:

protective clothing and self-contained breathing apparatus.

CO/CO₂ Hazardous combustion products:

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.

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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 an 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.

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.

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

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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

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

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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.

PVC or rubber gloves. The protective gloves used must meet the requirements of Hand protection:

89/686/EEC.

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: Colorless, clear liquid

Characteristic odour of alcohol Odour:

Odour threshold: 178 mg/m³

pH: 5.3 Melting/freezing point: -114 °C

Initial boiling point: 78.2 °C (1013 hPa) Boiling range: Not available. Flash point: 15 °C (closed cup)

Evaporation rate: Ethanol 95% 1.4, Water 0.3

Flammability (solid/gas): Not available. Upper/lower flammability or 2.5 - 13.5 V%

explosive limits:

Vapour pressure: 57.3 hPa (20 °C), 70 hPa (25 °C)

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Vapour density: 1.8 kg/m³

Relative density: 0,806 (20 °C), 0,809 (25 °C)

Solubility: Unlimited miscibility with diethyl ether, chloroform, petrol and benzene.

Solubility in water: Unlimited miscible with water

Partition coefficient -0.45

(n-octanol/water):

Auto-ignition temperature: 363 °C

Decomposition temperature: > 700 (secondary literature) Thermally stable, no self-decomposing substance

Viscosity: Dynamic: 1.2 mPa.s (20 °C)

Kinematic: 1.52 μm2/s (20 °C)

Explosive properties: None
Oxidising properties: None

9.2 Other information

Conductivity: 130 000 pS/m

Dissociation constant: 15.8 pKa (20 °C) Heat of combustion: 29 685 kJ/kg

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

General information: 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.

Spontaneous polymerization: No polymerization.

10.4 Conditions to avoid

Heat, sources of ignition, light, humidity.

10.5 Incompatible materials

Strong oxidizing or reducing compounds, acids (chlorides, anhydrides), strong peroxides, strong bases, alkali metals, alkaline earth metals, alkali oxides. Reacts slowly with calcium hypochlorite, silver oxide and ammonia causing fire and explosion hazard. Reacts violently with strong oxidants such as nitric acid, silver nitrate, mercury nitrate or magnesium perchlorate causing fire and explosion hazard.

10.6 Hazardous decomposition products

 CO, CO_2

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Lowest published lethal dose (child, oral): 2000 mg/kg

LD50 (oral, mouse): 3450 mg/kg LD50 (oral, rat): 7060 mg/kg

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LC50 (inhalation, rat): 20000 ppm/10h

After inhalation of vapors, slight mucosal irritation may develop and the substance may be absorbed. Eye contact can also cause mild irritation. Ingestion of large quantities gives rise to nausea, dizziness and vomiting, euphoria, intoxication,

narcosis and paralysis of the breathing.

Skin corrosion/irritation: Not irritating (rabbit, OECD 404)

Not 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)

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: In vitro bacterial reverse mutation tests: negative with and without metabolic

activation (Salmonella typhimurium, OECD 471, Ames test).

In vitro bacterial reverse mutation tests: positive and negative without metabolic

activation (Escherichia coli, no test with guidelines).

In vitro cytotoxicity in mammalian cells: negative without metabolic activation

(mouse lymphoma, OECD 476).

In vitro chromosome aberration: negative with no metabolic activation (hamster

ovary cells, OECD 473).

In vivo micro nucleus test: negative (mouse, OECD 475). In vivo chromosome aberration: negative (hamster, OECD 475)

Research into dominant lethal cause: positive and negative (mouse, OECD 478) No evidence for germ cell mutagenicity, provided data from humans exclusively

related to excessive alcohol consumption are disregarded.

Based on the available data, the classification criteria of one of the categories of this

hazard class are not met.

Carcinogenicity: NOAEL (carcinogenicity, rat, 24 months, OECD 451): > 3,000 mg/kgbw

NOAEL (carcinogenicity, mouse, female, 24 mo, EPA OPPTS 870.4200): > 4 400

mg/kgbw

NOAEL (carcinogenicity, mouse, male, 24 months, EPA OPPTS 870.4200): > 4 250

mg/kgbw

BMDL10 (carcinogenicity, mouse, male, 24 months): 1,400 mg/kg

Results from epidemiological studies, based on excessive consumption of ethanol in

alcoholic beverages, cannot be extrapolated to the determination of the

carcinogenic properties of ethanol in the workplace. The only epidemiological data that could be relevant in this context could be attributed to the development of breast cancer. However, the available data do not appear to contain an increased cancer risk that would be expected in comparable workplace conditions.

Based on the available data, the classification criteria of one of the categories of this

hazard class are not met.

Reproductive toxicity: Fertility:

NOAEL (fertility, oral, mouse, young animal/litter, sperm effects in F1 generation,

OECD 416): 13.8 g/kg

NOAEL (fertility, oral, mouse, male, other effects in F1 generation, OECD 416): 21.5

g/kg

NOAEL (fertility, inhalation, rat, male, OECD 415): > 23 mg/L

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Teratogenicity:

NOAEC (teratogenicity, inhalation, rat, OECD 414): > 20,000 ppm

NOAEL (teratogenicity, oral, rat, OECD 414): > 6.7 g/kg NOAEL (teratogenicity, oral, mouse, OECD 414): 13.7 g/kg

Foetotoxicity:

NOAEL (foetotoxicity, oral, rat, OECD 414): > 5.7 g/kg

Embryotoxicity

NOAEL (embryotoxicity, oral, rat, OECD 414): > 3.6 g/kg

Maternal toxicity:

NOAEC (maternal, inhalation, rat, OECD 414): > 3.6 g/kg 16,000 ppm

NOAEL (maternal) (oral, rat, OECD 414): 8.2 g/kg NOAEL (maternal) (oral, mouse, OECD 414): <2.2 g/kg

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.

STOT-repeated exposure: Neurotoxicity:

NOEL (neurotoxicity): (nominal): <1,000 ppm NOAEL (behavioral development): ≥ 1,600 mg/m³

Aspiration Hazard: No indication that the substance causes inhalation toxicity.

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

Ecotoxicological information (ethanol):
Toxicity to fish: *L. idus* LC50: 8140 mg/l
Bacterial toxicity: *Ps. putida* EG5: 6500 mg/l
Algae toxicity: *Sc. quadricauda* EG5: 5000 mg/l
Protozoan toxicity: *E. sulcatum* EG5: 65 mg/l

12.2 Persistence and degradability

The product is easily biodegradable and evaporates quickly in water.

12.3 Bioaccumulative potential

Bioaccumulation is not expected (log P (o/w) <1).

12.4 Mobility in soil

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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

If applied correctly, no impairment of the functionality of wastewater treatment plants is to be expected. Harmful to aquatic organisms at high concentrations.

Further ecological data (ethanol): BOD5: 0.93 - 1.67 g/g; CSB: 1.99 - 2.11 g/g; ThOD: 2.10 g/g; BOD: 63% of ThOD; CSB: 90% of ThOD. No environmental problems are expected if the product is handled and used with care and

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: There are no uniform EC regulations for the disposal of chemicals or waste. Chemical waste is usually special waste. Disposal should be in accordance with local government regulations. We recommend that you contact the appropriate competent authority for your region if necessary.

Packaging: Disposal in accordance with local government regulations. Unless otherwise provided by law, contaminated empty containers can be rinsed with water that can then be removed with the waste water; the packaging can then be recycled or treated as household waste.

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), Ш

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.

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

Not within the scope of Marpol Appendix 3.

14.8 Additional transport information

Dangerous goods label: 3

Tunnel category (ADR/RID): (D/E)

Hazard identification number (ADR/RID): 33

Limited quantity (LQ): 5 L (ADR/RID, ADN), 5 L (LQ4) (IMDG, IATA/ICAO)

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Exempt amount (ADR/RID, IATA/ICAO): E2

ERICard (ADR/RID): 3-09

Emergency measures in case of accident (IMO/IMDG): in case of fire: Echo (F-E); in case of spillage: Delta (S-D) 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.

Safety phrases: S2 Keep out of the reach of children.

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 GoodsIUPAC: International Union of Pure and Applied ChemistryPBT: 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 Bioaccumalative

16.3 Key literature references/sources for data

European Chemicals Agency.

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

16.4 Method of classification in case of mixture

Not available.

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.

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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 FRAVER NV info@magis-pharma.be