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

1.1 Product identifier

Product name: Poppy flower liquid extract

Papaveris rhoeados floris extractum fluidum

Klaproosbloem vloeibaar extract Extrait fluide de fleur de coquelicot

Mohnblumen Flüssigextrakt

N° CAS: 84696-43-5 N° EC: 283-651-5

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. Liq. 3 H226 Eye Irrit. 2 H319

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):





Signal word(s): Attention

Flammable

Irritant

Hazard statements:

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H226 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.

P240 Ground and bond container and receiving equipment.

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

P242 Use non-sparking tools.

P243 Take action to prevent static discharges.
P264 Wash hands thoroughly after handling.

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

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with

water or shower.

P370+P378 In case of fire: Use CO₂, extinguishing powder or water spray to extinguish.

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.

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

P501 Dispose of contents/container in accordance with local/regional/national/inter-

national regulations.

Additional applicable label

elements:

Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Characteristics of the preparation: N° CAS: 84696-43-5

N° EINECS: 283-651-5

Chemical characterization of the compound contributing to the danger: Ethanol

IUPAC name: Ethanol

Synonyms: Ethyl alcohol

Alcohol

 N° CAS: 64-17-5 N° EC: 200-578-6 Molecular Formula: C_2H_6O

52.100

Content: Concentration: 15 - 20%

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SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation: Move to fresh air. In case of unconsciousness, lie down, put the person on his side

and inform the doctor (also in case of malaise).

After skin contact: Remove contaminated clothing immediately. Rinse with water/shower. Consult a

doctor if necessary.

After eye contact: Rinse with plenty of water. Eyelids should be held away from the eyeball to ensure

complete flushing. Remove contact lenses if worn and if they can be easily removed.

Seek medical attention if irritation persists.

After ingestion: If vomiting occurs, place in side position and rinse mouth with water. Seek medical

attention if necessary.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Carbon dioxide (CO₂), extinguishing powder, water spray or foam.

Fight large fires with alcohol-resistant foam.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Hazardous combustion products and associated risks: Release of carbon monoxide and carbon dioxide. Vapours may form an explosive mixture with air. Runoff to sewer may cause fire or explosion.

5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Depending on the extent of the fire, it will be necessary to use heat

protective clothing, self-contained breathing equipment, gloves,

goggles or face shields and boots.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Wear gloves, safety glasses and respiratory protection. Ventilate the area. Keep unprotected persons away.

For emergency responders

Wear gloves, safety glasses and respiratory protection. Ventilate the area. Keep unprotected persons away.

6.2 Environmental precautions

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Do not discharge into drains, surface water or groundwater.

6.3 Methods and material for containment and cleaning up

Collect with absorbent material and ensure adequate ventilation.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Keep away from heat/sparks/open flames/hot surfaces. Do not

smoke. Keep container tightly closed.

Personal protection: Not available.

Technical protective measures: Do not use spark-producing tools. Take precautionary measures

against electrostatic discharges (Regulation 1272/2008). Handle in a

ventilated room (dust extraction if possible).

Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Not available.

Conditions for safe storage, including any

incompatibilities:

Store in a HDPE plastic container, in a dry and dark place, at a temperature between 5-25 °C (shelf life: see specification sheet).

Storage – away from: Store protected from light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limit values

No OEL determined on a 15 - 20% hydroalcoholic solution Exposure value for pure ethanol (Belgium): 1907 mg/m³/8h Exposure value for pure ethanol (Spain): 1910 mg/m³/8h

Exposure value for pure ethanol (Estonia, Sweden): 1000 mg/m^3 Exposure limit value for pure ethanol (Switzerland): 1920 mg/m^3

Exposure limit value for pure ethanol (USA): 1900 mg/m³

Average exposure value for pure ethanol (France): 1900 mg/m³/8h

MAK limit value for pure ethanol (Germany): 1900 mg/m³

8.2 Exposure controls

Appropriate engineering control

Not available.

Individual protection measures

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Eye/face protection: Wearing of protective glasses is recommended.

Skin protection: Wearing a gown is recommended.

Hand protection: Wearing gloves (nitrile type) is recommended.

Respiratory protection: Work in a ventilated area, use a respiratory mask if used in large quantities.

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Not available. Odour: Not available. Odour threshold: Not available. Not determined. pH: Not determined. Melting/freezing point: Initial boiling point: Not determined. Boiling range: Not determined. Flash point: Not determined. Not determined. Evaporation rate: Not determined. Flammability (solid/gas): Upper/lower flammability or

explosive limits:

Not available.

Not determined. Vapour pressure: Vapour density: Not available. Relative density: 0.90 - 1.25

Solubility: Fat solubility: To be tested.

To be tested. Solubility in water: Partition coefficient Not available.

(n-octanol/water):

Not determined. Auto-ignition temperature: Decomposition temperature: Not determined. Not available. Viscosity:

Explosion hazard: Not determined. Explosive properties:

Oxidising properties: Not applicable.

9.2 Other information

Not available.

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SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Not available.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Heat.

Take precautionary measures against static discharge.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Combustion may generate carbon oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Not available. Skin corrosion/irritation: Not available. Serious eye damage/irritation: Not available. Respiratory/skin sensitisation: Not available. Germ cell mutagenicity: Not available. Carcinogenicity: Not available. Reproductive toxicity: Not available. Summary of evaluation of the Not available.

CMR properties:

STOT-single exposure: Not available.
STOT-repeated exposure: Not available.
Aspiration Hazard: Not available.

Other: No toxicity determined.

No values determined.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: Causes serious eye irritation.

Skin contact:

Inhalation:

Not available.

Ingestion:

Not available.

Not available.

Not available.

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SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

The product is expected to degrade rapidly in wastewater treatment plants.

Biodegradable product.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Avoid reject into the drains, surface water, the underground sheets of water and nature.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Do not dispose of with household waste. Do not allow to enter sewers. Disposal according to national, regional and local regulations.

Contaminated packaging: No special provisions, according to national, regional and local regulations.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

ADR/ RID(Land),IMDG(Sea),

1197

IATA/ICAO (Air):

14.2 UN proper shipping name

ADR/RID(Land),IMDG(Sea),

EXTRAITS LIQUIDES

IATA/ICAO (Air):

14.3 Transport hazard class(es)

ADR/RID(Land),IMDG(Sea),

3 (Flammable liquids)

IATA/ICAO (Air):

14.4 Packing group

ADR/RID(Land),IMDG(Sea),

Ш

IATA/ICAO (Air):

14.5 Environmental hazards

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ADR/RID(Land),IMDG(Sea),

Not available.

IATA/ICAO (Air):

14.6 Special precautions for user

Not available.

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

Not available.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Flammable Irritan

Risk phrases: R10 Flammable.

R36 Irritating to eyes.

Safety phrases: S3 Keep in a cool place.

S7 Keep container tightly closed.

S9 Keep container in a well-ventilated place.

S16 Keep away from sources of ignition – No smoking.

S28 After contact with skin, wash immediately with plenty of water.

 ${\tt S33\ Take\ precautionary\ measures\ against\ static\ discharges.}$

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

15.2 Chemical safety assessment

Not available.

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

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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 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

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

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