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

1.1 Product identifier

Product name: Ricinus oil

Ricini oleum virginale

Ricinusolie Huile de Ricin Rizinusöl

N° CAS: 8001-79-4 N° EC: 232-293-8

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

Not classified according to the Regulation (EC) No 1272/2008.

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s):

Not applicable.

Not applicable.

Not applicable.

Precautionary statements:

Additional applicable label

Not applicable.

Not applicable.

elements:

2.3 Other hazards

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Not classified according to the Directive 1999/45/EC and to the Regulation (EC) No 1272/2008.

Health Hazards: None identified.

Physio-chemical Hazards: None identified. Environmental Hazards: None identified.

The product doesn't meet the criteria for classification as hazardous in accordance with Regulation (EC) No 1272/2008, is not persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) as defined in Annex XIII of Regulation (EC) No 1907/2006 (REACH), and is not included in the ECHA candidate list of substances of very high concern. Provision of a Safety Data Sheet (SDS) is thus not mandatory (REACH Art. 31). This Product Safety Sheet (PSS) is a voluntary presentation of certain information that may assist the user in the handling of the substance.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Fatty oil obtained by cold expression from the seeds of Ricinus communis L. A suitable antioxidant may be added.

Product name: Ricinus oil

IUPAC name: 2,3-bis[[(Z)-12-hydroxyoctadec-9-enoyl]oxy]propyl (Z)-12-hydroxyoctadec-9-enoate

Synonyms: Ricinus Communis Seed Oil

Castor oil

N° CAS: 8001-79-4
N° EC: 232-293-8
Molecular Formula: $C_{57}H_{104}O_9$
Content: Not available.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation: Inhalation is not a pertinent exposure route for the product due to this physical

aspect and/or its composition.

After skin contact: Liberally bathe affected body parts with water and soap.

After eye contact: Rinse out carefully with plenty of water with the eyelid held wide open.

After ingestion: If the person is conscious, rinse mouth with water. Do not induce vomiting without

medical advice.

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

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Suitable extinguishing media: Foam, dry chemical powder, carbon dioxide.

Unsuitable extinguishing media: Water.

5.2 Special hazards arising from the substance/mixture

Combustion dangers: Combustible material, low hazard.

5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Respiratory and eye protection required for fire fighting personnel

exposed to fumes or smoke.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

See section 8.

For emergency responders

See section 8.

6.2 Environmental precautions

Limit the leak using soil or sand. Avoid penetration into watercourses and sewers. If the product goes into them or it contaminates vegetation, warn the competent authorities.

6.3 Methods and material for containment and cleaning up

Collect the product for a possible re-utilisation, or for elimination. Absorb it with inactive material. Then, wash the involved area and materials with water.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Personal protection:

Technical protective measures:

Handling:

Not available.

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: In airtight, well-filled containers.

Conditions for safe storage, including any Keep in a cool place.

incompatibilities: Store in the original full closed drum or container to prevent over

oxidation.

Storage – away from: Store protected from light.

7.3 Specific end use(s)

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Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Not available.

Individual protection measures

Eye/face protection: Wear safety glasses.

Skin protection: Wear clothes with full skin protection.

Hand protection: Wear gloves.

Not necessary for normal use. Respiratory protection:

Thermal hazards: Not determined.

Environmental exposure control

None.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Clear at 40 °C, slightly yellow, viscous, hygroscopic liquid.

Odour: Characteristic Odour threshold: Not available. pH: Not available.

-10 °C Melting/freezing point: Initial boiling point: > 350 °C

Boiling range: Not available. Flash point: > 285 °C Evaporation rate: None.

Not available. Flammability (solid/gas): Upper/lower flammability or Not available.

explosive limits:

Not available. Vapour pressure: Vapour density: Not available. About 0.958. Relative density: Solubility: Soluble in oils.

slightly soluble in light petroleum, miscible with ethanol (96 per cent) and with

glacial acetic acid.

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Solubility in water: Non soluble. Partition coefficient Not available.

(n-octanol/water):

448 °C Auto-ignition temperature:

Decomposition temperature: Not available.

Viscosity: 950 - 1100 cP (20 °C)

Explosive properties: Not available.

Oxidising properties: None.

9.2 Other information

Refractive index (20 °C): 1,4769.

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

None in particular.

10.5 Incompatible materials

None in particular.

10.6 Hazardous decomposition products

None in particular.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Oral LD_{50} (rat): > 2000 mg/kg (Non toxic) Acute toxicity:

Skin corrosion/irritation: Non irritant.

Serious eye damage/irritation: Eye irritation 10%: Slight irritation of the mucous membranes may occur.

Respiratory/skin sensitisation: Non sensitizing. Germ cell mutagenicity: Not available. Not available. Carcinogenicity: Reproductive toxicity: Not available. Summary of evaluation of the

CMR properties:

CMR effect: None.

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

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Aspiration Hazard: Not available.

Other: CIR status: Safe.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:

Skin contact:

Inhalation:

Ingestion:

Aspiration:

Not available.

Not available.

Not available.

Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not determined.

12.2 Persistence and degradability

Not determined.

12.3 Bioaccumulative potential

Not determined.

12.4 Mobility in soil

Not determined.

12.5 Results of PBT and vPvB assessment

Not determined.

12.6 Other adverse effects

Avoid discharge into environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

If it is possible, recover the product.

Send to the authorised disposal or burning plants under controlled conditions.

Follow domestic and national effective laws.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

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

Not classified.

IATA/ICAO (Air):

14.2 UN proper shipping name

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

Not classified.

IATA/ICAO (Air):

14.3 Transport hazard class(es)

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

IATA/ICAO (Air):

Not classified.

14.4 Packing group

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

1DG(Sea), Not classified.

IATA/ICAO (Air):

14.5 Environmental hazards

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

Not classified.

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

According to regulations:

ADR (acc. Council Dir. 94/55/EC) & RID (acc. Council Dir. 96/49/EC) – not dangerous.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not applicable.
Risk phrases: Not applicable.
Safety phrases: Not applicable.

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
 PBT: Persistent, Bioaccumulative and Toxic substance

RID: Regulations Concerning the International Transport of Dangerous Goods by Rail

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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 applicable.

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

FRAVER NV

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