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

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

1.1 Product identifier

Product name: Cellulose acetate phthalate solution

Cellulosi acetas phthalas solutio
Cellulose acetaatftalaatoplossing
Solution d'acétophtalate de cellulose
Celluloseacetat-Phthalat-Lösung

N° CAS: 9004-38-0 N° EC: 618-382-8

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

Flam. Liq. 2 H225 Eye Irrit. 2 H319 STOT SE 2 H336 Repr. 1 H360

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):





Signal word(s): Danger

Hazard statements:

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H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

H360 May damage fertility or the unborn child.

Precautionary statements:

P201 Obtain special instructions before use.

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

No smoking.

P233 Keep container tightly closed.

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

Highly flammable liquid and vapour.

P312 Call a POISON CENTER/doctor/... if you feel unwell.

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

water [or shower].

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

Additional applicable label

elements:

Not applicable.

2.3 Other hazards

None.

H225

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Cellulose acetate phthalate solution

IUPAC name: Cellulose Acetate Phthalate

Synonyms: Cellacefate

Cellulose, acetate hydrogen 1,2-benzenedicarboxylate

 $\begin{array}{lll} \mbox{N° CAS:} & 9004-38-0 \\ \mbox{N° EC:} & 618-382-8 \\ \mbox{Molecular Formula:} & \mbox{C}_{116}\mbox{H}_{116}\mbox{O}_{64} \\ \mbox{Content:} & 100\ \% \\ \end{array}$

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation: Move to fresh air. Treat symptomatically. Get medical attention if symptoms persist.

After skin contact: Wash with soap and water. Get medical attention if symptoms occur.

After eye contact: Any material that contacts the eye should be washed out immediately with water. If

easy to do, remove contact lenses. Get medical attention if symptoms persist.

After ingestion: Seek medical advice. Material is not expected to be absorbed from the

gastrointestinal tract so that induction of vomiting should not be necessary.

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4.2 Most important symptoms and effects, both acute and delayed

No known chronic or acute health risks.

4.3 Indication of any immediate medical attention and special treatment needed

Hazards: None known.

Treatment: Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon

dioxide.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Powdered material may form explosives dust- air mixtures.

5.3 Advice for firefighters

Surrounding fires: General Fire Hazards: Material can accumulate static charges which

may cause electrical spark (ignition source). Use proper bonding

and/or grounding procedures.

Minimize dust generation & accumulation.

Protection against fire: Wear self contained breathing apparatus for fire fighting if

necessary.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid dust formation. Avoid breathing vapors, mist or gas. Wear appropriate personal protective equipment.

For emergency responders

Avoid dust formation. Avoid breathing vapors, mist or gas. Wear appropriate personal protective equipment.

6.2 Environmental precautions

Not regarded as dangerous for the enviornment.

6.3 Methods and material for containment and cleaning up

Sweep up and scoop. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Not available.

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Technical protective measures: Provide appropriate exhaust ventilation at places where dust is

Not available.

formed. Normal measures for preventive fire protection.

Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: In tight container.

Conditions for safe storage, including any

incompatibilities:

Personal protection:

Store in cool place. Keep container tightly closed in a dry place.

Storage – away from: Protected from heat and light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering control

General industrial hygiene practice.

Individual protection measures

Eye/face protection: Use equipment for eye protection tested and approved under appropriate

government standards such as NIOSH (US) or EN 166(EU).

Skin protection: Choose body protection in relation to its type, to the concentration and amount of

dangerous substances, and to the specific work-place., The type of protective equipment must be selected according to the concentration and amount of the

dangerous substance at the specific workplace.

Hand protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove

removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with

applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive

89/686/EEC and the standard EN 374 derived from it.

Respiratory protection: Respiratory protection is not required. Where protection from nuisance levels of

dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards

such as NIOSH (US) or CEN (EU).

Thermal hazards: Not determined.

Environmental exposure control

Not available.

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9.1 Information on basic physical and chemical properties

Appearance: Form: powder/flakes

Colour: white to off white

Odour: Odourless. Odour threshold: Not available. Not available. Melting/freezing point: Not available. Initial boiling point: Not available. Not available. Boiling range: Flash point: Not available.

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

explosive limits: Vapour pressure:

Not available.

Vapour density: Not available. Relative density: Not available. Solubility: Not available.

Solubility in water: Insoluble in water. Partition coefficient

(n-octanol/water):

Not available.

Auto-ignition temperature: Not available. Decomposition temperature: Not available. Viscosity: Not available. Not available. Explosive properties: Oxidising properties: Not available.

9.2 Other information

Molecular Weight: 2,534.12 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Stable.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Not available.

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10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

Carbon monoxide. Carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: ORAL LD_{50} : > 5,000 mg/kg (rat) Skin corrosion/irritation: LD_{50} : > 2,000 mg/kg (rabbit)

Serious eye damage/irritation: Not available.

Respiratory/skin sensitisation: LC_{s_0} : > 5.21 mg/l (4 h) (rat) Maximum attainable concentration - zero mortality

Germ cell mutagenicity: Not available.

Carcinogenicity: IARC: No component of this product present at levels greater than or equal to 0.1%

is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity: Developmental Toxicity - mouse – Oral

Specific Developmental Abnormalitie: Musculoskeletal system.

Summary of evaluation of the

CMR properties:

Not available.

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

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: May cause eye irritation.

Skin contact: May be harmful if absorbed through skin. May cause skin irritation.

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion: May be harmful if swallowed.

Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

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Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Disposal methods: Dispose of waste and residues in accordance with local authority requirements. Incinerate in accordance with local authority requirements.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

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

Not classified.

14.2 UN proper shipping name

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

Not dangerous goods

IATA/ICAO (Air):

14.3 Transport hazard class(es)

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

Not classified.

IATA/ICAO (Air):

14.4 Packing group

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

Not classified.

IATA/ICAO (Air):

14.5 Environmental hazards

ADR/RID: no

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

IMDG Marine pollutant: no

IATA: no

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

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Hazard symbol:





Danger

Risk phrases: R11 Highly flammable.

R36 Irritating to eyes. R60 May impair fertility.

R61 May cause harm to the unborn child.

R67 Vapours may cause drowsiness and dizziness.

Safety phrases: S3/7/9 Keep container tightly closed in a cool, well-ventilated place.

S15 Keep away from heat.

S16 Keep away from sources of ignition - No smoking.

S27/28 After contact with skin, take off immediately all contaminated clothing, and

wash immediately with plenty of soap and water.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection. S45 In case of accident or if you feel unwell seek medical advice immediately

(show the label where possible.

S53 Avoid exposure - obtain special instructions before use.

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

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.

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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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