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

1.1 Product identifier

Product name: Acetone

Acetonum Aceton Acétone Aceton 67-64-1

N° CAS: 67-64-1 N° EC: 200-662-2

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

België

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

Flammable liquids (category 2) H225
STOT (category 3) H319
Eye irritation (category 2) H336
EUH066

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.

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H336 May cause drowsiness or dizziness.

EUH066 Repeated exposure may cause skin dryness or cracking.

Precautionary statements:

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

No smoking.

P243 Take precautionary measures against static discharge.

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

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if

present and easy to do – continue rinsing.

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

P501 Dispose of contents/container to an accredited waste processing company.

Additional applicable label

elements:

Not applicable.

2.3 Other hazards

Inhalation of vapors may cause mild irritation of mucous membranes.

Can be absorbed into the body by inhalation and through the skin.

The product can have effects: gastrointestinal tract, symptoms of poisoning, headache, nausea, dizziness and unconsciousness.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Acetone

IUPAC name: Propan-2-one Synonyms: Propanone

2-Propanone

N° CAS: 67-64-1 N° EC: 200-662-2 Molecular Formula: C_3H_6O Content: 100%

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Take off immediately all contaminated clothing. Move victim to fresh air. Keep victim

warm and at rest. In case of unconsciousness, apply recovery position and seek

medical attention.

After inhalation: Remove from exposure. Keep warm and at rest and provide fresh air. Provide oxygen

or artificial respiration if necessary. Get medical attention immediately.

After skin contact: Take off immediately all contaminated clothing. Wash off immediately with soap and

plenty of water. Get medical attention.

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After eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 10

minutes. Get medical attention immediately.

After ingestion: If swallowed, seek medical advice immediately and show the container or label. DO

NOT induce vomiting. Rinse mouth and take activated charcoal.

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

Symptoms of poisoning can occur a few hours later. Keep under medical supervision for at least 48 hours. Artificial respiration and / or oxygen may be necessary. Danger of delayed induction of pulmonary edema.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Alcohol resistant foam. Dry powder. Water spray. Carbon Dioxide.

Unsuitable extinguishing media: Powerful water jet.

5.2 Special hazards arising from the substance/mixture

In case of insufficient combustion, the following can be formed: carbon monoxide, carbon dioxide, vapors can form explosive mixtures with air.

5.3 Advice for firefighters

Surrounding fires: Remove all ignition sources. Cool containers / tank with water spray.

Protection against fire: Wear self-contained breathing apparatus and protective clothing.

Complete suit for protection against chemicals. Flame retardant

protective clothing.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Keep people away from and upwind of spill / leak. Use personal protective equipment.

For emergency responders

Keep people away from and upwind of spill / leak. Use personal protective equipment.

6.2 Environmental precautions

Try to stop a leak without personal risk. Should not be released into the environment. Prevent the product from entering the sewage system. Local authorities should be notified of significant spills that cannot be contained. Consider the risk of explosion.

6.3 Methods and material for containment and cleaning up

Provide adequate ventilation, especially in enclosed areas. Large spills must be mechanically picked up (by pumps) for disposal.

Small amounts: Soak up with inert absorbent material. Remove all ignition sources. Only use non-sparking tools. Vapors are heavier than air and may spread along floors. Watch out for fire recoil. The product evaporates easily.

6.4 Reference to other sections

For personal protection see section 8.

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SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Provide good ventilation / exhaustion at the workplace.

Personal protection: Do not smoke.

Technical protective measures: Keep ignition sources away - no smoking. Take measures against

static electricity discharge. Protect from heat.

Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Keep in a cool and dry place in tightly closed containers.

Conditions for safe storage, including any

incompatibilities:

Keep tanks tightly closed.

Storage – away from: Not available.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

TWA: 500 ppm, 1.210 mg/m³ TGG 8 hr: 500 ppm, 1.210 mg/m³ TGG 15 min: 1000 ppm, 2.420 mg/m³

8.2 Exposure controls

Appropriate engineering control

Only use explosion-proof equipment. Provide adequate ventilation.

Individual protection measures

Eye/face protection: Safety glasses with side shields according to EN166.

Skin protection: Wear protective clothing when working with chemicals. Flame retardant protective

clothing. Safety shoes according to EN345-347.

Hand protection: Wear gloves in case of prolonged or repeated contact. Butyl rubber: penetration time

> 480 min, glove thickness 0.5 mm. Observe the regulations regarding permeability and breakthrough time, as provided by the supplier of the gloves. Also take into account specific local conditions of use, such as cut hazard, wear and contact time. The selected protective gloves must comply with the specifications of EU directive

89/686 / EEC and the standard EN374 derived from it.

Respiratory protection: In case of insufficient ventilation wear suitable respiratory equipment. Wear mask

with AX particle filter.

Thermal hazards: Not determined.

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Environmental exposure control

Try to stop a leak without personal risk. Should not be released into the environment. Prevent product from entering the sewage system. Local authorities should be notified of significant spills that cannot be contained. Consider the risk of explosion.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Liquid, colorless.

Odour: Sweet, aromatic.

Odour threshold: 19.8 ppm.

pH: 7, concentration 10.00 g/L.

Melting/freezing point: -94.7 °C. Initial boiling point: 56 °C.

Boiling range: Not available.

Flash point: -17 °C. Evaporation rate: 2.0.

Flammability (solid/gas): Flammable.

Upper/lower flammability or

2.5% - 14.3% (V)

explosive limits:

Vapour pressure: 20 °C: 240 hPa, 50 °C: 800 hPa.

Vapour density: 2.1 (20 °C).
Relative density: 0.79 (20 °C)

Solubility: Fat soluble. Miscible with most organic solvents.

Solubility in water: Completely soluble.

Partition coefficient - 0.24.

(n-octanol/water):

Auto-ignition temperature: 465 °C

Decomposition temperature: Not available.

Viscosity: 0.32 mPa.s (20 °C)

Explosive properties: Not explosive.

Oxidising properties: Not classified as oxidizing.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Reacts with bases.

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10.2 Chemical stability

Vapors can form explosive mixtures with air. Vapors are heavier than air and may spread along floors. Watch out for fire recoil.

10.3 Possibility of hazardous reactions

No dangerous reactions have been observed under normal conditions.

10.4 Conditions to avoid

Keep away from heat, ignition sources. Exposure to light.

10.5 Incompatible materials

Can attack many plastics, rubbers and coatings. Keep away from bases, oxidizing agents and amines.

10.6 Hazardous decomposition products

Carbon monoxide, carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Oral: LD50: 5.800 mg/kg (rat); Inhalation: LD50: 76 mg/L (4h, rat); Dermal: LD50 >

15.800 mg/kg (rabbit).

Skin corrosion/irritation: Contact with skin may cause irritation, prolonged skin contact may defat the skin and

produce dermatitis.

Serious eye damage/irritation: Irritating to eyes.

Respiratory/skin sensitisation: No effect known.

Germ cell mutagenicity: In vitro and in vivo tests did not show mutagenic effects.

Carcinogenicity: Mouse: exposure 1 yr, skin, negative.

Reproductive toxicity: Fertility and developmental disorder studies did not show any effect on fertility.

Summary of evaluation of the

CMR properties:

Not available.

STOT-single exposure: May cause drowsiness or dizziness.

STOT-repeated exposure: Liver and kidney injury can occur. The product can affect blood and bone marrow.

Prolonged skin contact may defat the skin and cause dermatitis. The substance is not

classified as a specific target organ toxicant, repeated exposure.

Aspiration Hazard: No aspiration toxicity classification.

Other: Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: May cause eye irritation.

Skin contact: Can be absorbed into the body through the skin.

Inhalation: Can be absorbed into the body by inhalation.

Ingestion: Can cause gastrointestinal disturbances.

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Aspiration: Not available.

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SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 5,540 mg / L, 96 h, static test, Fresh water; LC50 (European alver (Alburnus alburnus)): 11,000 mg / L, 96 h, static test, Sea water.

Daphnia and other aquatic invertebrates: LC50 (Daphnia pulex (water flea)): 8,800 mg / L, 48 h, static test, Fresh water; LC50 (Artemia salina): 2,100 mg / L, 24 h, static test, Sea water.

Algae: NOEC (Microcystis aeruginosa): 530 mg / L, 8 d, static test, Fresh water; NOEC (Pro-center minimum): 430 mg / l, 96 h, Sea water.

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 2,212 mg / L, 28 d, Daphnia magna (Water flea), flow-through test, Fresh water.

Toxicity to bacteria: EC12 (Bacteria): 1,000 mg / L, 30 min, Respiration inhibition of activated sludge.

Ecotoxicology Assessment, Chronic aquatic toxicity: This product has no known ecotoxicological effects.

12.2 Persistence and degradability

Biodegradability: Biodegradation: 91%, Method: OECD Test Guideline 301 B, Remarks: Readily biodegradable, Biodegradation: 84%, Related to: Theoretical Oxygen Demand, Test Type: Activated Sludge, Biodegradation: 100% Stability in water: Hydrolysis: (0%)

Photodegradation: Test Type: Air, Half-life (direct photolysis): 10 d

12.3 Bioaccumulative potential

Bioconcentration factor (BCF): 3, Method: calculated, Remarks: Bioaccumulation not expected: Partition coefficient (notanol / water) log Kow <3

12.4 Mobility in soil

High. Note: the product evaporates easily.

12.5 Results of PBT and vPvB assessment

This substance is not considered to be persistent, bioaccumulating nor toxic (PBT). This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

12.6 Other adverse effects

The product should not be allowed to enter drains, water courses or the soil.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Dispose of as hazardous waste in accordance with local and national regulations. Do not dispose of with household waste. List of recommended waste codes / waste designations according to Eural: 07 01 04 * (other organic solvents, washing liquids and mother liquors)

Contaminated packaging: Dispose of as hazardous waste in accordance with local and national regulations.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), UN 1090 IATA/ICAO (Air):

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14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

ADR/RID(Land),IMDG(Sea), 3

IATA/ICAO (Air):

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), ADR: II, 33, 3, D/E IATA/ICAO (Air): IMDG: F-E, S-D

14.5 Environmental hazards

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

DR/ RID(Land), IIVIDG(Sea),

IATA/ICAO (Air):

No environmental hazards

14.6 Special precautions for user

No specific instructions necessary.

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

Ship type: N / A, pollution category: Z.

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:

×

*

Xi Irritant.

F Flammable

Risk phrases: R11 Highly flammable

R36 Irritating to eyes

R66 Repeated exposure may cause skin dryness or cracking

R67 Vapours may cause drowsiness and dizziness

Safety phrases: Not available

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)

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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 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

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