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

FORM-06-14-01 (V00)

Page 1/11

ΕN

Publication: 15/07/2022 Revision: 15/07/2022

Version: 00



ACIDUM ACETICUM GLACIALE

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

1.1 Product identifier

Product name: Acetic acid, glacial

Acidum aceticum glaciale

Glaciaal azijnzuur

Acétique glacial (acide)

Essigsäure

N° CAS: 64-19-7 N° EC: 200-580-7

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

Flammable liquid (category 3) H226 Skin corrosion (category 1A) H314 Eye damage (category 1) H318

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):





Signal word(s): Danger

Hazard statements:

H226 Flammable liquid and vapour.

H314 Causes severe skin burns and eye damage.

H318 Causes serious eye damage.

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

ACIDUM ACETICUM GLACIALE

FORM-06-14-01 (V00) Page 2/11

ΕN

Publication: 15/07/2022 Revision: 15/07/2022

Version: 00



Precautionary statements:

P102 Keep out of reach of children

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

No smoking.

Take action to prevent static discharges. P243

Do not breathe dust/fume/gas/mist/vapours/spray. P260

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

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

if present and easy to do. Continue rinsing.

Dispose of contents/container to authorized disposal company or local collection P501

center.

Additional applicable label

elements:



2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Acetic acid, glacial

IUPAC name: Acetic acid Synonyms: Not applicable.

N° CAS: 64-19-7 N° EC: 200-580-7 Molecular Formula: $C_2H_4C_2$

Content: 99.0% m/m to 100.5% m/m

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: In case of accident or unwellness, seek medical advice immediately (show directions

> for use or safety data sheet if possible). Take off immediately all contaminated clothing. Wash contaminated clothing before reuse. If unconscious place in recovery

position and seek medical advice. Do not leave affected person unattended.

Remove person to fresh air and keep comfortable for breathing. Get medical After inhalation:

advice/attention if you feel unwell.

After contact with skin, wash immediately with plenty of water. Remove After skin contact:

contaminated, saturated clothing immediately. If skin irritation occurs: Get medical

advice/attention.

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

ACIDUM ACETICUM GLACIALE

FORM-06-14-01 (V00)

Page 3/11

ΕN

15/07/2022 Publication: 15/07/2022 Revision:

Version: 00



In case of contact with eyes flush immediately with plenty of flowing water for 10 to After eye contact:

15 minutes holding eyelids apart and consult an ophthalmologist. Remove contact

lenses, if present and easy to do. Continue rinsing. Get immediate medical

advice/attention.

(refer to section 8).

If accidentally swallowed rinse the mouth with plenty of water (only if the person is After ingestion:

conscious) and obtain immediate medical attention. Do NOT induce vomiting.

First aider: Pay attention to self-protection! Wear personal protection equipment

Self-protection of the first

aider:

4.2 Most important symptoms and effects, both acute and delayed

The following symptoms may occur: Causes serious eye damage. Causes severe burns. Inhalation of vapours or spray/mists: Irritation to respiratory tract, Headache, Nausea, Dizziness, Vomiting, Dyspnoea, Pulmonary oedema.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray jet, alcohol resistant foam, extinguishing powder,

carbon dioxide (CO₂).

Not available. Unsuitable extinguishing media:

5.2 Special hazards arising from the substance/mixture

Flammable liquid and vapour. Gases/vapours, irritant. Vapours are heavier than air, spread along floors and form explosive mixtures with air. Heating causes rise in pressure with risk of bursting.

5.3 Advice for firefighters

Surrounding fires: Wear a self-contained breathing apparatus and chemical protective

clothing.

Protection against fire: Wear a self-contained breathing apparatus and chemical protective

Hazardous combustion products: In case of fire may be liberated: carbon oxides (COx).

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Do not breathe gas/vapour/aerosol. Provide adequate ventilation. Avoid contact with skin, eyes and clothes. Immediately remove any contaminated clothing, shoes or stockings. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Remove persons to safety.

Protective equipment: Wear protective gloves/protective clothing/eye protection/face protection. See section 8.

For emergency responders

Personal protection equipment: Personal protection equipment: see section 8.

6.2 Environmental precautions

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

ACIDUM ACETICUM GLACIALE

FORM-06-14-01 (V00)

Page 4/11

ΕN

Publication: 15/07/2022 Revision: 15/07/2022

Version: 00



The product is an acid. Before discharge into sewage plants the product normally needs to be neutralised. Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

6.3 Methods and material for containment and cleaning up

For containment: Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Collect in closed and suitable containers for disposal. Handling larger quantities: Prevent spread over a wide area (e.g. by containment or oil barriers).

For cleaning up: Water

6.4 Reference to other sections

Safe handling: see section 7.

Personal protection equipment: see section 8.

Disposal: see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Do not breathe gas/vapour/aerosol. Provide adequate ventilation.

Always close containers tightly after the removal of product. Conditions to avoid: Aerosol or mist formation. May be corrosive to metals. Formation of: hydrogen (H₂)! Avoid contact with eyes and skin. Take off immediately all contaminated clothing and wash it before reuse. Wear personal protection equipment (refer to section

8).

Personal protection:

Technical protective measures:

Not available.

Not available.

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Material, acid-resistant. Floors should be impervious, resistant to

liquids and easy to clean. Keep/Store only in original container.
Unsuitable container/equipment material: Aluminium, light metals,

iron, zinc.

Conditions for safe storage, including any

incompatibilities:

Keep container tightly closed in a cool, well-ventilated place.

Recommended storage temperature: \geq 16 °C.

Storage – away from: Do not store together with: alkalines, Oxidizing agent. Keep/Store

away from combustible materials. Keep away from food, drink and $% \left(1\right) =\left(1\right) \left(1\right) \left($

animal feedingstuffs.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

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

FORM-06-14-01 (V00)

Page 5/11 15/07/2022

ΕN

Publication: 15/07/2022 Revision: 15/07/2022

Version: 00



ACIDUM ACETICUM GLACIALE

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limit values

Occupational exposure limit values					
Substance name	1.	1. Long-term occupational exposure limit value			
	2.	Short-term occupational esposure limit value			
	3.	Instantaneous value			
	4.	Monitoring and observation processes			
	5.	Remark			
Acetic acid	1.	10 ppm (25 mg/m³)			
CAS No.: 64-19-7	2.	20 ppm (50 mg/m³)			
Acetic acid	1.	10 ppm (25 mg/m ³)			
		11 \ 0. ,			
	Acetic acid CAS No.: 64-19-7	Substance name 1. 2. 3. 4. 5. Acetic acid 1. CAS No.: 64-19-7 2.			

Biological limit values
 Not available.

DNEL-/PNEC-values

Substance name	DNEL value	1. 2.	DNEL type Exposure route
Acetic acid CAS No.: 64-19-7	25 mg/m ³	1. 2.	DNEL worker DNEL acute inhalative (local)
Acetic acid CAS No.: 64-19-7	25 mg/m ³	1. 2.	DNEL consumer DNEL acute inhalative (local)

Substance name	PNEC value	1.	PNEC type
Acetic acid CAS No.: 64-19-7	3.058 mg/L	1.	PNEC aquatic, freshwater
Acetic acid CAS No.: 64-19-7	0.3058 mg/L	1.	PNEC aquatic, marine water
Acetic acid CAS No.: 64-19-7	30.58 mg/L	1.	PNEC aquatic, intermittent release
Acetic acid CAS No.: 64-19-7	11.38 ml/kg	1.	PNEC sediment, freshwater
Acetic acid CAS No.: 64-19-7	1.138 ml/kg	1.	PNEC sediment, marine water
Acetic acid CAS No.: 64-19-7	85 mg/L	1.	PNEC sewage treatment plant (STP)

8.2 Exposure controls

Appropriate engineering control

Technical measures and the application of suitable work processes have priority over personal protection equipment. Provide adequate ventilation as well as local exhaustion at critical locations.

Individual protection measures

Eye/face protection: Eye glasses with side protection (EN 166).

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

ACIDUM ACETICUM GLACIALE

FORM-06-14-01 (V00) Page 6/11

15/07/2022

ΕN

Publication: 15/07/2022 Revision: 15/07/2022

Version: 00



Skin protection: Tested protective gloves must be worn (EN ISO 374).

Suitable material: IIR (Butyl rubber)
Thickness of the glove material: 0,5 mm

Breakthrough time (maximum wearing time): ≤ 60 min

The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. In the case of wanting to use the gloves again, clean them before

taking off and air them well.

Hand protection: Not determined.

Respiratory protection: Usually no personal respirative protection necessary. Provide adequate ventilation.

If workplace limits are exceeded, a respiratory protection approved for this particular job must be worn. Combination filtering device (EN 14387), Filter type:

ABEK.

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: Crystalline mass or clean, colourless, volatile liquid

Odour: stinging like Acetic acid

Odour threshold: 4 mg/m^3 pH: 1.3 - 1.8

Melting/freezing point: Melting point: 15 - 16 °C, freezing point: not determined.

Initial boiling point: $118.1 \,^{\circ}\text{C}$ Boiling range: $118.1 \,^{\circ}\text{C}$ Flash point: $39 \,^{\circ}\text{C}$

Evaporation rate: Not determined. Flammability (solid/gas): Not determined. Upper/lower flammability or 4-17 Vol-%

explosive limits:

expressive mines.

Vapour pressure: 16 hPa

Vapour density: 2.07

Relative density: 1.05 g/mL

Solubility: Miscible with water, with ethanol (96%) and with methylene chloride.

Solubility in water: completely miscible

Partition coefficient

(n-octanol/water):

Auto-ignition temperature:

485 °C

-0.17

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

FORM-06-14-01 (V00)

Page 7/11

ΕN

Publication: 15/07/2022 Revision: 15/07/2022

Version: 00



ACIDUM ACETICUM GLACIALE

Decomposition temperature: Not determined.

Viscosity: Not determined.

Explosive properties: Not determined.

9.2 Other information

Oxidising properties:

Molecular weight: 60,05 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Corrosive and flammable. Moisture-sensitive. Reaction with: Alkali (lye); Oxidising agent, strong.

Not determined.

10.2 Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions. Vapours can form explosive mixtures with air. This material can accumulate static charge by flow or agitation and can be ignited by static discharge. Exothermic reaction with: Alkali (lye), concentrated; Oxidising agent, strong (Formation of: Gases/vapours, flammable). Reaction with: metals (including their alloys). Caution! Formation of: hydrogen (H₂). Hazardous polymerisation: with Acetaldehyde.

10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep cool. Protect from sunlight. Protect from moisture.

10.5 Incompatible materials

Alkali (lye); Metal, base; Oxidizing agent

10.6 Hazardous decomposition products

No known hazardous decomposition products. In case of fire may be liberated: carbon oxides (COx).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Not available.

Skin corrosion/irritation: Method OECD 404, Rabbit: Causes severe burns.

Serious eye damage/irritation: Method OECD 405, Rabbit: Causes serious eye damage.

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: Inhalation of vapours or spray/mists: May cause respiratory irritation.

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

FORM-06-14-01 (V00) Page 8/11

ΕN

Publication: 15/07/2022 Revision: 15/07/2022

Version: 00



ACIDUM ACETICUM GLACIALE

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:

Skin contact:

Not available.

Inhalation:

Not available.

Not available.

Not available.

Not available.

Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Biodegradation: Method OECD 301B: Readily biodegradable (according to OECD criteria).

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water: -0.17

Accumulation / Evaluation: No indication of bioaccumulation potential.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

CAS No.	Substance name	Results of PBT and vPvB assessment
64-19-7	Acetic acid	/

This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste treatment options

Appropriate disposal / Product: Dispose of waste according to applicable legislation. Consult the appropriate local waste disposal expert about waste disposal.

Appropriate disposal / Package: Dispose of waste according to applicable legislation. Completely emptied packages can be recycled.

Other disposal recommendations: Collect in closed and suitable containers for disposal. Waste for disposal is to be classified and labelled. Protect from sunlight. Store in a well-ventilated place. Vapours can form explosive mixtures with air. Do not allow to enter into surface water or drains.

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

FORM-06-14-01 (V00) Page 9/11

ΕN

Publication: 15/07/2022 Revision: 15/07/2022

Version: 00



ACIDUM ACETICUM GLACIALE

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

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

2789

IATA/ICAO (Air):

14.2 UN proper shipping name

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

ACETIC ACID, GLACIAL

IATA/ICAO (Air):

14.3 Transport hazard class(es)

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

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),

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

Not available.

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

For this substance a chemical safety assessment has been carried out.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

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

ACIDUM ACETICUM GLACIALE

FORM-06-14-01 (V00) Page 10/11

ΕN

Publication: 15/07/2022 Revision: 15/07/2022

Version: 00



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

Hazard classes and hazard categories	Hazard statements	Classification procedure
Serious eye damage/eye irritation (Eye Dam. 1)	H318: Causes serious eye damage.	Test data
Flammable liquids (Flam. Liq. 3)	H226: Flammable liquid and vapour.	Test data
Skin corrosion/irritation (Skin Corr. 1A)	H314 : Causes severe skin burns and eye damage.	Test data

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

ACIDUM ACETICUM GLACIALE

FORM-06-14-01 (V00)

Page 11/11 15/07/2022

ΕN

Publication: 15/07/2022 Revision: 15/07/2022

Version: 00



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16.8 Department issuing MSDS

Quality Department FRAVER NV info@magis-pharma.be