

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

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Publication: 19/09/2022

Revision: XX/XX/XXXX

Version: 00



## KALII ASPARTAS RACEMICUS HEMIHYDRICUS

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

#### 1.1 Product identifier

Product name:	Potassium hydrogen aspartate hemihydrate racemic Kalii aspartas racemicus hemihydricus Kaliumaspartaat hemihydraat racemisch Potassium (aspartate de) hemihydrate racémique Racemisches Kaliumhydrogenaspartat-Hemihydrat
N° CAS:	923-09-1
N° EC:	213-088-2

#### 1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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#### 1.3 Details of the supplier of the safety data sheet

Company:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts 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 a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. This substance is not classified as dangerous according to Directive 67/548/EEC.

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):	Not applicable.
Signal word(s):	Not applicable.
Hazard statements:	Not applicable.
Precautionary statements:	Not applicable.
Additional applicable label elements:	Not applicable.

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### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Potassium hydrogen aspartate hemihydrate racemic
IUPAC name:	Potassium 2-amino-3-carboxypropanoate
Synonyms:	Potassium hydrogen DL-aspartate L-Aspartic acid, monopotassium salt
N° CAS:	923-09-1
N° EC:	213-088-2
Molecular Formula:	$C_4H_6KNO_4 \cdot 0.5 H_2O$
Content:	98.0 to 102.0 percent (calculated on the anhydrous substance)

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

After inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.
After skin contact:	In case of contact with skin, wash immediately with plenty of soap and water.
After eye contact:	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
After ingestion:	If swallowed, wash out mouth with water provided person is conscious; call a physician.

### 4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects: Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

Potential chronic health effects: Repeated or prolonged exposure is not known to aggravate medical condition.

### 4.3 Indication of any immediate medical attention and special treatment needed

Notes to physicians: Treat symptomatically.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media:	Water spray, dry chemical powder, carbon dioxide.
Unsuitable extinguishing media:	Not available.

### 5.2 Special hazards arising from the substance/mixture

Unusual fire and explosions hazards: Formation of nitrogen and carbon oxides during product combustion.

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### 5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.
Hazardous combustion products:	Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Avoid raising dust.

#### For emergency responders

Avoid raising dust.

### 6.2 Environmental precautions

Not available.

### 6.3 Methods and material for containment and cleaning up

Place in appropriate container.  
Flush spill area with copious amounts of water.

### 6.4 Reference to other sections

Not available.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:	Not available.
Personal protection:	The product is not dangerous, nevertheless wear protecting equipment.
Technical protective measures:	Not available.
Handling:	Not available.

### 7.2 Conditions for safe storage, including any incompatibilities

Storage:	In an airtight container.
Conditions for safe storage, including any incompatibilities:	Store at room temperature in the original container.
Storage – away from:	Keep away from heat, sparks and flames. Protect from light.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Not available.

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### 8.2 Exposure controls

#### Appropriate engineering control

Installing an efficient exhaust system.

#### Individual protection measures

Eye/face protection: Goggles (not essential).

Skin protection: Work clothes and safety shoes. General guidelines of good industrial hygiene.

Hand protection: Gloves (not essential).

Respiratory protection: Not determined.

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: White crystalline powder or colourless crystals.

Odour: Odourless.

Odour threshold: Not available.

pH: 5.5 – 6.5 (1% in H<sub>2</sub>O) (20 °C)

Melting/freezing point: Not available.

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Flammability (solid/gas): Not available.

Upper/lower flammability or explosive limits: Not available.

Vapour pressure: Not available.

Vapour density: Not available.

Relative density: Not available.

Solubility: Organic solvents: insoluble.

Solubility in water: Easily soluble in water: 40 g/l (25 °C)

Partition coefficient (n-octanol/water): Not available.

Auto-ignition temperature: Not available.

Decomposition temperature: Not available.

Viscosity: Not available.

Explosive properties: Not available.

Oxidising properties: Not available.

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### 9.2 Other information

Not available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Product stable at room temperature for at least 3 years.

### 10.2 Chemical stability

Product stable at room temperature for at least 3 years.

### 10.3 Possibility of hazardous reactions

Not available.

### 10.4 Conditions to avoid

High temperature, humidity or direct sunlight.

### 10.5 Incompatible materials

Oxidisers.

### 10.6 Hazardous decomposition products

Formation of nitrogen and carbon oxides at product combustion.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	The product seems to have a very low toxicity. LD50 (ipr/mus): > 6 g/kg (as DL-Aspartic acid)
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 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:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.

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Ingestion: Not available.

Aspiration: Not available.

### SECTION 12: ECOLOGICAL INFORMATION

#### 12.1 Toxicity

Ecotoxicity: The product seems to have a very low toxicity.

Water toxicity: The product seems to have a very low toxicity.

#### 12.2 Persistence and degradability

Biodegradability: Microbiologically degradable.

Degradability: Microbiologically degradable.

#### 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

Not available.

### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

Product: If recycling is not possible, dispose of in accordance with local regulations for the disposal of solid waste.

Product microbiologically degradable.

Containers: General rules for disposal of containers containing chemical materials.

### 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),  
IATA/ICAO (Air) : Not classified.

##### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

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### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

### 14.6 Special precautions for user

Not available.

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

Not applicable.

### 14.8 Additional transport information

DOT Classification: Not a DOT controlled material.

## 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: S22 Do not breathe dust.  
S24/25 Avoid contact with skin and eyes.

### 15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

## 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 Bioaccumulative

### 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

FAC SECUNDUM ARTEM NV

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