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

1.1 Product identifier

Product name: Potassium citrate

Kalii citras Kaliumcitraat

Potassium (citrate de)

Kaliumcitrat

N° CAS: 6100-05-6 N° EC: 612-062-1

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: 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 (CLP).

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:

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2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Potassium citrate

IUPAC name: Tripotassium;2-hydroxypropane-1,2,3-tricarboxylate;hydrate

Synonyms: Potassium citrate monohydrate

Tripotassium citrate monohydrate

 N° CAS:
 6100-05-6

 N° EC:
 612-062-1

 Molecular Formula:
 $C_6H_5K_3O_7,H_2O$

Content: 99.0 per cent to 101.0 per cent (anhydrous substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Consult a doctor. Show the safety data sheet to the doctor on duty.

After inhalation: Take to fresh air. If breathing is irregular, call a doctor immediately. Only give

artificial respiration if breathing stops or under medical supervision.

After skin contact: Wash immediately with plenty of soap and water for at least 15 minutes. Remove all

contaminated clothing immediately. Get medical attention if irritation develops and

persists.

After eye contact: Remove contact lenses and rinse immediately with plenty of water, including under

eyelids, for at least 15 minutes. Get medical attention.

After ingestion: If conscious, give the victim plenty of water to drink. Never give anything by mouth

to an unconscious person. Call a doctor immediately.

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

Suitable extinguishing media: Foam, dry powder, carbon dioxide, sand, water mist.

Neighbouring fires (containers exposed to fire): Water spray or fog.

Unsuitable extinguishing media: Direct water jet.

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5.2 Special hazards arising from the substance/mixture

Emits toxic fumes in case of fire (carbon monoxide).

5.3 Advice for firefighters

Surrounding fires: Cool containers with water to prevent decomposition of product

and development of potential health hazards. Always use full fire protection. Collect water from entering sewage system. Dispose of

contaminated water used for extinguishing and residues in

accordance with current regulations.

Protection against fire: Helmet with visor, flame retardant clothing (jacket and trousers with

straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the whole face of the operator or the car (self protective) in case of large amounts of smoke, a self-contained breathing apparatus (EN 137).

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 vapours, mist or gas.

For emergency responders

Avoid dust formation. Avoid breathing vapours, mist or gas.

6.2 Environmental precautions

Do not allow product to enter sewage system or ground water.

6.3 Methods and material for containment and cleaning up

Collect dry (with water it forms slippery layers) and dispose of the residues. Do not raise dust. Rinse afterwards.

6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Handle the product after consulting this safety data sheet.

Personal protection: Use dust masks if deemed necessary.

Technical protective measures: Adequate extraction should be provided where dust is formed.

Keep dust formation and deposition levels low.

Handling: Dust explosion may occur.

7.2 Conditions for safe storage, including any incompatibilities

Storage: In an airtight container.

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Conditions for safe storage, including any

incompatibilities:

Storage – away from:

Store in a cool place.

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

Keep away from incompatible materials (section 10).

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

It is recommended that the ACGIH occupational exposure limit values for unclassified inert dusts be considered in the risk assessment process. If these limits are exceeded, we recommend the use of a P-type filter whose class (1, 2 or 3) should be chosen depending on the outcome of the risk assessment.

8.2 Exposure controls

Appropriate engineering control

Observe the usual safety precautions when handling chemicals.

Hygiene measures: Handle with appropriate industrial hygiene precautions, and observe safety practices.

Individual protection measures

Eye/face protection: Not necessary. Skin protection: Not necessary.

Hand protection: Not necessary. Wash hands before breaks and after finishing work.

Respiratory protection: Where risk assessment shows that air-purifying respirators are appropriate, use dust

> mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or

CEN (EU).

Not determined. Thermal hazards:

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

White or almost white, granular powder or transparent crystals, hygroscopic. Appearance:

Odour: Characteristic. Odour threshold: Not available.

pH: 7 – 9 (5 % aqueous solution)

Melting/freezing point: > 180 °C

Initial boiling point: Not available. Boiling range: Not available. Flash point: Not available.

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Evaporation rate: Not available. Not available. Flammability (solid/gas):

Upper/lower flammability or

explosive limits:

Not available.

Vapour pressure:

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

Solubility: Practically insoluble in ethanol (96 per cent).

Very soluble in water: 640 g/l (20 °C) Solubility in water:

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.

9.2 Other information

VOC (directive 199/13/EC): 0 VOC (volatile carbon): 0

Molecular weight: 324.41 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The product is stable if used properly. No special conditions.

10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

Under normal conditions of use and storage, no hazardous reactions are expected.

No hazards specifically mentioned.

10.4 Conditions to avoid

None in particular. However, please observe the usual precautions. Avoid dust formation. Keep away from heat, sparks and open flames. Protect from moisture. Protect from heat and direct sunlight.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Not available.

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Oral LD₅₀ (rat): 3 250 mg/kg Acute toxicity:

Dermal LD₅₀: > 2 000 mg/kg

Skin corrosion/irritation: Not available. Not available. Serious eye damage/irritation: Respiratory/skin sensitisation: Not available. Germ cell mutagenicity: Not available. Not available. Carcinogenicity: Reproductive toxicity: Not available. Summary of evaluation of the Not available.

CMR properties:

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

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

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SECTION 13: DISPOSAL CONSIDERATIONS 13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated container: Dispose of as unused product.

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)

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(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

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

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.

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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 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 FAC SECUNDUM ARTEM NV info@magis-pharma.be