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## **KALII SORBAS**

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

#### 1.1 Product identifier

Product name: Potassium sorbate

Kalii sorbas Kaliumsorbaat

Potassium (sorbate de)

Kaliumsorbat

N° CAS: 590-00-1 N° EC: 611-771-3

### 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: Magis-Pharma NV

Neerlandweg 24 2610 Wilrijk 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

Skin irritation (category 2) H315 Eye irritation (category 2) H319

## 2.2 Label elements

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

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Precautionary statements:

P264 Wash thoroughly after handling.

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P270 Do not eat, drink or smoke when using this product.

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.

P302 + P352 IF ON SKIN: Wash with plenty of water.

P332 + P313 If skin irritation occurs: Get medical advice/attention.
P337 + P313 If eye irritation persists: Get medical advice/attention.

Additional applicable label

elements:

Not applicable.

## 2.3 Other hazards

Not available.

#### **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

#### 3.1 Substances

Product name: Potassium sorbate

IUPAC name: Potassium;(2E,4E)-hexa-2,4-dienoate

Synonyms: Sorbistat potassium

Sorbic acid potassium salt

 N° CAS:
 590-00-1

 N° EC:
 611-771-3

 Molecular Formula:
 C<sub>6</sub>H<sub>7</sub>KO<sub>2</sub>

Content: 99.0 % to 101.0 % (dried substance).

#### 3.2 Mixtures

Contains no other components or impurities that may influence the classification of the product.

#### **SECTION 4: FIRST AID MEASURES**

## 4.1 Description of first aid measures

General notes: Consult a physician. 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, also 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.

Self-protection of the first

aider: Not applicable.

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

It is not expected to present a significant hazard under anticipated conditions of normal use.

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### 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.

Unsuitable extinguishing media: Direct water jet.

## 5.2 Special hazards arising from the substance/mixture

In case of fire, fumes harmful to health may be produced.

#### 5.3 Advice for firefighters

Surrounding fires: Cool containers with water to avoid decomposition of the product

and the development of potential health hazards. Always use complete fire protection. Collect water that should not enter sewage system. Dispose of contaminated water used to extinguish and the

remains of the second in accordance with current regulations.

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

straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the entire face of the operator or the car (self-protector) in the 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

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

Equip clean-up personnel with appropriate protective equipment. Ventilate the area. Evacuate unnecessary personnel.

#### For emergency responders

Not available.

#### **6.2 Environmental precautions**

Prevent release to the environment. Prevent it from entering sewers and water pipes. If the product reaches sewers or public waterways, notify authorities.

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

Store away from other materials. If on the ground, sweep or scoop (shovel or similar) into suitable containers. Limit dust production.

#### 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.

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## **KALII SORBAS**

### **SECTION 7: HANDLING AND STORAGE**

#### 7.1 Precautions for safe handling

Precautions for safe handling: Wash thoroughly after handling. Do not eat, drink or smoke while

handling this product. Ask for special instructions before use.

Personal protection: Not available.

Technical protective measures: Ensure good ventilation of the processing area to avoid vapor

formation.

Handling: Not available.

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

Storage: Store in a ventilated place, in well-sealed containers, out of direct

sunlight, light and moisture, at room temperature.

Conditions for safe storage, including any

incompatibilities:

Not available.

Storage – away from: Away from all sources of combustion.

#### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

#### **SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

## 8.1 Control parameters

Not available.

### 8.2 Exposure controls

#### Appropriate engineering control

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must bear the CE marking attesting to compliance with applicable regulations. Provide an emergency shower with a visco-elastic tray.

### **Individual protection measures**

Eye/face protection: Protective face shields and safety goggles in accordance with EN166.

Skin protection: Choose body protection according to the amount and concentration of the hazardous

substance in the workplace.

Hand protection: Handle with gloves. The selected protective gloves must comply with the

specifications of EU Directive 89/686/EEC and the derived EN 374 standard.

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 (USA) or CEN

(EU).

Thermal hazards: Not determined.

#### **Environmental exposure control**

Not available.

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### **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

#### 9.1 Information on basic physical and chemical properties

Appearance: White or almost white powder or granules.

Odour: Not available. Odour threshold: Not available. pH: 7.4-10.6 Melting/freezing point:  $250 \, ^{\circ}\text{C}$ 

Initial boiling point:

Boiling range:

Not available.

Flash point:

Evaporation rate:

Flammability (solid/gas):

Upper/lower flammability or

Not available.

Not available.

Not available.

explosive limits:

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

Solubility: Slightly soluble in ethanol (96 %).

Solubility in water: Very soluble in water.

Partition coefficient -1.72

(n-octanol/water):

Auto-ignition temperature: > 210 °C

Decomposition temperature: 178 °C

Viscosity: Not available. Explosive properties: Not available. Oxidising properties: Not available.

#### 9.2 Other information

VOC (Directive 2010/75/EC): 0 VOC (Volatile carbon): 0

### **SECTION 10: STABILITY AND REACTIVITY**

#### 10.1 Reactivity

No special conditions. Stable under recommended handling and storage conditions (see section 7).

#### 10.2 Chemical stability

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

#### 10.3 Possibility of hazardous reactions

Not available.

## 10.4 Conditions to avoid

Avoid any type of incorrect handling: high pressures and/or temperatures. Direct sunlight.

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# 10.5 Incompatible materials

Strong oxidising agents, aluminium, zinc and tin.

#### 10.6 Hazardous decomposition products

Decomposition by heat can produce toxic CO and CO<sub>2</sub> fumes.

#### **SECTION 11: TOXICOLOGICAL INFORMATION**

#### 11.1 Information on toxicological effects

Acute toxicity: Acute oral toxicity (LD<sub>50</sub>, mouse): 10500 mg/kg

Acute dermal toxicity (LD50, rabbit): 2000 mg/kg

Skin corrosion/irritation: Causes skin irritation.

Serious eye damage/irritation: Causes serious eye irritation.

Respiratory/skin sensitisation: Not available.
Germ cell mutagenicity: Not available.
Carcinogenicity: Not available.

Reproductive toxicity: This product should be handled with care due to its possible teratogenic effects,

which may reduce human fertility.

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.

Not available.

Inhalation:

Not available.

Ingestion:

Not available.

Not available.

Not available.

Not available.

## **SECTION 12: ECOLOGICAL INFORMATION**

#### 12.1 Toxicity

Fish toxicity (LC<sub>50</sub>): 500 mg/L/96h Crustacean toxicity (EC<sub>50</sub>): 480 mg/L/48h 982 mg/L/72h

## 12.2 Persistence and degradability

Biodegradable.

#### 12.3 Bioaccumulative potential

Low bioaccumulation level.

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## 12.4 Mobility in soil

Not available.

#### 12.5 Results of PBT and vPvB assessment

Not available.

#### 12.6 Other adverse effects

Avoid release into the environment.

### **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 to dispose 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 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

It is not dangerous in transport.

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## **KALII SORBAS**

#### **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

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.

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

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(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