

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 1/9

Publication: 26/04/2022

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Version: 00

## PHENOXYMETHYLPENICILLINUM KALICUM



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

#### 1.1 Product identifier

Product name:	Phenoxyethylpenicillin potassium Phenoxyethylpenicillinum kalicum Fenoxymethylpenicilline kalium Phénoxyméthylpénicilline potassique Phenoxyethylpenicillin-Kalium
N° CAS:	132-98-9
N° EC:	205-086-5

#### 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

Acute Tox. 4	H302
Skin Sens. 1	H317
Resp. Sens. 1	H334

#### 2.2 Label elements

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

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H302 Harmful if swallowed.

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 2/9

Publication: 26/04/2022

Revision: 26/04/2022

Version: 00



## PHENOXYMETHYLPENICILLINUM KALICUM

H317	May cause an allergic reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary statements:	
P285	In case of inadequate ventilation wear respiratory protection.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P270	Do not eat, drink or smoke when using this product.
P264	Wash thoroughly after handling.
P272	Contaminated work clothing should not be allowed out of the work place.
P342+P311	If experiencing respiratory symptoms: Call a poison center or doctor/physician.
P301+P312	IF SWALLOWED: Call a poison center or doctor/physician if you feel unwell.
P363	Wash contaminated clothing before reuse.
P304+P341	IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P330	Rinse mouth.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
Additional applicable label elements:	

### 2.3 Other hazards

Results of PBT and vPvB assessment:

PBT: Not applicable.

vPvB: Not applicable.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Phenoxyethylpenicillin potassium
IUPAC name:	Potassium (2S,5R,6R)-3,3-dimethyl-7-oxo-6-[(2-phenoxyacetyl)amino]-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate.
Synonyms:	Penicillin V potassium Potassium penicillin V Beepen-VK
N° CAS:	132-98-9
N° EC:	205-086-5
Molecular Formula:	C <sub>16</sub> H <sub>17</sub> KN <sub>2</sub> O <sub>5</sub> S
Content:	95.0 per cent to 102.0 per cent for the sum of the percentage contents of phenoxyethylpenicillin potassium and 4-hydroxyphenoxyethylpenicillin potassium (anhydrous substance).

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 3/9

Publication: 26/04/2022

Revision: 26/04/2022

Version: 00



## PHENOXYMETHYLPENICILLINUM KALICUM

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

General notes:	If you feel unwell, seek medical advice (show the label where possible).
After inhalation:	Remove victim immediately from source of exposure. Supply fresh air. Seek medical treatment in case of complaints.
After skin contact:	Remove contaminated clothing. Rinse with water. If skin irritation continues, consult a doctor.
After eye contact:	Remove contact lenses. Immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persist.
After ingestion:	Rinse mouth thoroughly. Call for a doctor immediately. Show the packing or label to the doctor.

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

The severity of the symptoms described will vary dependant of the concentration and the length of exposure. May cause an asthma-like shortness of breath. Harmful if swallowed. Gastrointestinal symptoms, including upset stomach. May cause an allergic skin reaction.

### 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:	Water spray, dry chemical powder, carbon dioxide.
Unsuitable extinguishing media:	Do not use water jet, as it may spread the fire.

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

In case of fire, the following can be released: Toxic gases/vapours, carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>), nitrogen oxides (NO<sub>x</sub>), sulphurous gases (SO<sub>x</sub>).

### 5.3 Advice for firefighters

Surrounding fires:	Cool endangered receptacles with water spray. Keep run-off water of sewers and water sources. Dike for water control.
Protection against fire:	Wear self-contained respiratory protective device. Wear fully protective suit.
Hazardous combustion products:	Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

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

#### For non-emergency personnel

Wear protective equipment. Keep unprotected persons away. Keep away from ignition sources. Do not inhale dust/smoke/mist. Avoid contact with eyes and skin. Ensure adequate ventilation.

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 4/9

Publication: 26/04/2022

Revision: 26/04/2022

Version: 00



## PHENOXYMETHYLPENICILLINUM KALICUM

### For emergency responders

Wear protective equipment. Keep unprotected persons away. Keep away from ignition sources. Do not inhale dust/smoke/mist. Avoid contact with eyes and skin. Ensure adequate ventilation.

### 6.2 Environmental precautions

Do not allow to enter sewers/surface or ground water.

Avoid creating dust.

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

Collect powder using special dust vacuum cleaner with particle filter or carefully sweep into closed container.

Clean the area with water.

Dispose of the material collected according to regulations.

### 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:

Usual safety precautions should be observed to ensure safe handling. Prevent formation of dust. Avoid contact with eyes and skin. Do not inhale dust/smoke/mist. Smoking, eating and drinking should be prohibited in application area.

Information about fire and explosion protection: Keep away from heat, sparks and open flame. Keep ignition sources away.

Personal protection:

Not available.

Technical protective measures:

Ensure good ventilation/exhaustion at the workplace.

Handling:

Wash hands before breaks and at the end of work. Remove and wash contaminated clothing before re-use.

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

Storage:

Store only in the original receptacle.

Conditions for safe storage, including any incompatibilities:

Keep container tightly sealed. Keep cool, dry, ventilated storage and closed containers.

Storage – away from:

Protect from light. Keep out of sunlight. Keep away from heat. Water sensitive materials. Protect from moisture. Store separated from: Strong oxidizing agents, alcohols, glycols, strong acids, strong alkali.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 5/9

Publication: 26/04/2022

Revision: 26/04/2022

Version: 00



## PHENOXYMETHYLPENICILLINUM KALICUM

### 8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information: This is based on data that was valid at the time of writing. Use engineering controls to reduce air contamination.

### 8.2 Exposure controls

#### Appropriate engineering control

General protective and hygienic measures: The usual precautionary measures are to be adhered to when handling chemicals. Ensure adequate ventilation. Prevent formation of dust. Avoid contact with eyes and skin. Do not inhale dust/smoke/mist. Wash hands before breaks and the end of work. Remove and wash contaminated clothing before re-use. Do not eat, drink or smoke while working. Eyewash and safety shower facilities should be available when handling this product.

#### Individual protection measures

Eye/face protection: Safety glasses (EN 166).

Skin protection: Protective work clothing.

Hand protection: Appropriate Chemical Resistant gloves. DIN/EN 374. The glove material has to be impermeable and resistant to the product/the substance/the preparation.  
Penetration time of glove material: The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Respiratory protection: Dust proof mask – particle filter mask. Filter P2. NIOSH or European Standard EN 149 approved respirator.

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 or almost white, crystalline powder.

Odour: Not available.

Odour threshold: Not available.

pH: 5.5 to 7.5 in solution

Melting/freezing point: Not available.

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not applicable.

Evaporation rate: Not available.

Flammability (solid/gas): Not available.

Upper/lower flammability or explosive limits: Not available.

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 6/9

Publication: 26/04/2022

Revision: 26/04/2022

Version: 00



## PHENOXYMETHYLPENICILLINUM KALICUM

Vapour pressure:	Not applicable.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Practically insoluble in ethanol (96 per cent).
Solubility in water:	Freely soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Product is not self-igniting.
Decomposition temperature:	Not available.
Viscosity:	Not applicable.
Explosive properties:	Product does not present an explosion hazard.
Oxidising properties:	Not available.

### 9.2 Other information

Molecular weight: 460.4 g/mol

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Not available.

### 10.2 Chemical stability

Stable under recommended storage and handling conditions (See Section 7).

### 10.3 Possibility of hazardous reactions

Hazardous polymerisation: will not occur.

### 10.4 Conditions to avoid

High temperature and heat.  
Exposure to moisture.  
Water.  
Direct sunlight. Light.

### 10.5 Incompatible materials

Strong oxidizing agent, alcohol, glycols, strong acids, strong alkalis.

### 10.6 Hazardous decomposition products

Fire or high temperature create: Carbon monoxide (CO) and carbon dioxide (CO<sub>2</sub>), nitrogen oxides(NO<sub>x</sub>), sulphur oxides (SO<sub>x</sub>).

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Oral LD <sub>50</sub> (rat): > 1040 mg/kg
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 7/9

Publication: 26/04/2022

Revision: 26/04/2022

Version: 00



## PHENOXYMETHYLPENICILLINUM KALICUM

Respiratory/skin sensitisation: May cause sensitization by inhalation and skin contact.

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: Gastrointestinal symptoms, including upset stomach.

Additional toxicological information: The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version. When used and handled according to specification, the product does not have any harmful effects to our experience and the information provided to us.

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: No specific health warnings noted.

Skin contact: May cause sensitization by skin contact.

Inhalation: May cause sensitization by inhalation.

Ingestion: Harmful if swallowed.

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

PBT: Not applicable. vPvB: Not applicable.

### 12.6 Other adverse effects

General notes: Avoid transfer into the environment.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 8/9

Publication: 26/04/2022

Revision: 26/04/2022

Version: 00



## PHENOXYMETHYLPENICILLINUM KALICUM

Recommendation: Dispose of in accordance with Local Authority requirements.

Contaminated packaging: Recommendation: Disposal must be made according to official regulations.

### 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.

##### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Marine pollutant: No.

##### 14.6 Special precautions for user

Not applicable.

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

Not applicable.

##### 14.8 Additional transport information

Not dangerous according to the above specifications.

### SECTION 15: REGULATORY INFORMATION

#### 15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol:



Irritant  
Harmful

Risk phrases:

R22 Harmful if swallowed.

Safety phrases:

S20/21 When using do not eat, drink or smoke.

S23 Do not breathe dust/fume/gas/mist/vapours/spray.

S28 After contact with skin, wash immediately with plenty of water.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S38 In case of insufficient ventilation, wear suitable respiratory equipment.



# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 9/9

Publication: 26/04/2022

Revision: 26/04/2022

Version: 00



## PHENOXYMETHYLPENICILLINUM KALICUM

### 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.

<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.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA

# Material Safety Data Sheet

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

## PHENOXYMETHYLPENICILLINUM KALICUM

EN

FORM-06-14-01 (V00)

Page 10/9

Publication: 26/04/2022

Revision: 26/04/2022

Version: 00



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### 16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

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