

# MATERIAL SAFETY DATA SHEET

## 1. Identification of the substance/preparation and company

### Identification of the manufacturer

Biotika a.s.  
976 13 Slovenska Lupca 566  
Slovak Republic  
Telephone number: +421 48 4368 111

### Identification of the product

- 1.1. Trade name: Penicillin V Potassium  
Phenoxymethylpenicillin Potassium
- 1.2. Chemical name: 4-Thia-1-azabicyclo [3.2.0]heptane-2-carboxylic acid, 3,3-dimethyl-7-oxo-6-[(phenoxyacetyl)amino]-,monopotassium salt, [2S-(2a,5a,6b)]-.  
Monopotassium (2S,5R,6R)-3,3-dimethyl-7-oxo-6-(2-phenoxycetamido)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate[132-98-9].
- 1.3. Chemical family: Antibiotic
- 1.4. Formula:  $C_{16}H_{17}KN_2O_5S$
- 1.5. CAS No.: 132-98-9

## 2 Composition/information on ingredients

Penicillin V Potassium only

## 3 Hazards identification

Non toxic, LD<sub>50</sub> cannot be expressed, allergen, allergic reactions may occur in 2 - 5 % of the population.

## 4 First-aid measures

- 4.1. Eye contact: rinse out with water
- 4.2. Skin contact: rinse out with water
- 4.3. Inhalation: immediately see a doctor
- 4.4. Ingestion: see a doctor
- 4.5. Emergency first aid procedures: apply adrenalin, noradrenalin, hydrocortisone, anti-histaminic agents, calcium

## 5 Fire-fighting measures

- 5.1. Flammable limits: settled powder 410°C  
spun powder 580°C
- 5.2. Extinguishing media: CO<sub>2</sub>, water

## 6 Accidental release measures

- 6.1. Respiratory protection: prevent from excessive pulverization
- 6.2. Ventilation: common aeration
- 6.3. Skin protection: protective gloves
- 6.4. Eye protection: yes

## 7 Handling and storage

- 7.1. Storage precautions: keep in dry place, protected from light and moisture
- 7.2. Storage temperature: between +10°C to +25°C

## 8 Exposure controls/personal protection

- 8.1. Threshold limit value: Penicillin V Potassium is harmless per os by usual dose of 400 000

- units every 4 hours (7 - 10 days)
- 8.2. Effect of overexposure: In ultra sensitive humans: allergic reactions from urticaria to anaphylactic shock
- 8.3. Respiratory protection: prevent from excessive pulverization
- 8.4. Ventilation: common aeration
- 8.5. Skin protection: protective gloves
- 8.6. Eye protection: yes

### **9 Physical and chemical properties**

- 9.1. Appearance/state at 20°C: a white crystalline powder
- 9.2. Odor: a slight characteristic of penicillin
- 9.3. Specific gravity: 0.40 - 0.45
- 9.4. Molecular weight: 388.48
- 9.5. pH: 4.0 - 7.5
- 9.6. Solubility in water: freely soluble
- 9.7. Solubility in organic solvent: practically insoluble in ether, fatty oils and liquid paraffin

### **10 Stability and reactivity**

- 10.1. Stability: stable under common storage conditions
- 10.2. Material to avoid: stable under common storage conditions
- 10.3. Incompatibility: milk, milk products, cyclamates
- 10.4. Hazardous polymerization:
- Conditions to avoid: Penicillin V formed complexes in solutions with sucrose. In neutral and alkaline solutions with sucrose was reaction with the formation of sucrose-penicilloate esters. These might be antigenic

### **11 Toxicological information**

Non toxic

### **12 Ecological information**

There is no supposed effect on any ecosystem from those substances released as a consequence of normal production.

### **13 Disposal consideration**

- 13.1. In case that material is released or spilled: remove by usual means (sweep away, use vacuum cleaner, etc.)
- 13.2. Waste disposal method: burn down

### **14 Transport information**

Keep container closed and protect it from damage.

### **15 Regulatory information**

- Non toxic, allergen, non-explosive, flammable limits:
- |                |       |
|----------------|-------|
| settled powder | 410°C |
| spun powder    | 580°C |
- Extinguishing media: CO<sub>2</sub>, water

### **16 Other information**

Recommended uses: Penicillin is contraindicated at patients known to be hypersensitive to Penicillin and it should be used with caution at patients with known histories of allergy. It is not recommended for chronic, severe or deep seated infections.

On medical prescription only!

Sources of information: USP 31

Ph.Eur. 6th  
Company specification