

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 Calcium dihydrate
Phenoxyethylpenicillin Calcium dihydrate
- 1.2. Chemical name: IUPAC: Calcium bis [(2S,5R,6R)-3,3-dimethyl-7-oxo-6-(2-phenoxyacetamido)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate] dihydrate
Calcium bis [[2S-(2 α ,5 α ,6 β)]-3,3-dimethyl-7-oxo-6-[(phenoxyacetyl)amino]-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate] dihydrate
- 1.3. Chemical family: Antibiotic
- 1.4. Formula: $[C_{16}H_{17}N_2O_5S]_2 Ca \cdot 2H_2O$ or $C_{32}H_{34}CaN_4O_{10}S_2 \cdot 2H_2O$
- 1.5. CAS No.: 73368-74-8

2 Composition/information on ingredients

Penicillin V Calcium dihydrate only

3 Hazards identification

LD₅₀ 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: Slight fire hazard.
- 5.2. Extinguishing media: CO₂, 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 Calcium dihydrate is harmless per os by usual dose of 333 - 666 mg every 4 hours (7 - 10 days)
- 8.2. Effect of overexposure: In ultra sensitive humans: allergic reactions from urticaria to anaphylactic shock 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. Bulk density (powder): 680- 800 kg.m⁻³
- 9.4. Relative molecular weight: 774.9
- 9.5. pH: 5.0 - 7.5
- 9.6. Water content: 4.2 – 5.1 %
- 9.7. Solubility in water: slowly soluble in 120 parts water
- 9.8. Solubility in organic solvent: practically insoluble in ether, fatty oils and liquid paraffin

10 Stability and reactivity

- 10.1. Chemical Stability: stable under normal temperatures and pressures
- 10.2. Material to avoid: protect from moisture and extreme temperature
- 10.3. Incompatibility with Other Materials: strong oxidizing agents, acids, heavy metal salts.
- 10.4. Hazardous polymerization: will not occur

11 Toxicological information

Not available

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: waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Residue from fires extinguished with this material may be hazardous.

14 Transport information

Keep container closed and protect it from damage.

15 Regulatory information

Allergen, non-explosive, slight fire hazard.

Extinguishing media: CO₂, 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: The International Pharmacopoeia
Company specification