

## Penicillin V Calcium dihydrate Phenoxymethylpenicillin Calcium dihydrate

### Material Safety Data Sheet

Revision Date: January 04<sup>th</sup>, 2023

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| <b>1. SECTION: Identification of the substance/mixture and of the company undertaking.</b> |
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#### 1.1. Product identifier

**Product name:** Penicillin V Calcium dihydrate; Phenoxymethylpenicillin Calcium dihydrate  
**CAS:** 73368-74-8  
**UNII:** JJZ37N4V0X  
**INDEX:** None.  
**REACH reg.:** Deadlines according to REACH art. 23, has not expired.

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Use:** Antibiotic  
**Product name:** Penicillin V Calcium dihydrate; Phenoxymethylpenicillin Calcium dihydrate  
**Chemical family:** Beta-lactam antibiotics, penicillins  
**Synonyms:** Phenoxymethylpenicillin Calcium

#### 1.3. Details of the supplier of the safety data sheet


**Name:** BIOTIKA a.s.  
**Address:** Slovenska Lupca 566,  
PIN 976 13  
Slovak Republic  
**Tel.:** 00421/48/4368 111  
**Fax:** 00421/48/418 7060  
**E-mail:** biotika@biotika.eu.com


#### 1.4. Emergency telephone number

**Biotika a.s.:** 00421 48 4368 111

## 2. SECTION: Hazards identification.

### 2.1. Classification of the substance or mixture

|   |       |            |   |   |
|---|-------|------------|---|---|
|  | GHS07 | Acute Tox. | 4 | H302 Harmful if swallowed.                |
|   |       | Skin Sens. | 1 | H317 May cause an allergic skin reaction. |

|   |                        |             |   |   |
|---|------------------------|-------------|---|---|
|  | GHS08<br>Health hazard | Resp. Sens. | 1 | H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
|   |                        | Muta.       | 2 | H341 Suspected of causing genetic defects.                                      |

### 2.2. Label elements:

#### GHS label elements

The substance is classified and labeled according to the Globally Harmonized System (GHS).

#### Hazard pictograms

|   |       |   |       |
|---|-------|---|-------|
|  | GHS07 |  | GHS08 |
|---|-------|---|-------|

#### Signal word

Danger

#### Hazard statements


H302 Harmful if swallowed.  
 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
 H317 May cause an allergic skin reaction.  
 H341 Suspected of causing genetic defects.

## Precautionary statements


|           |   |
|-----------|---|
| P201      | Obtain special instructions before use.   |
| P202      | Do not handle until all safety precautions have been read and understood.                             |
| P261      | Avoid breathing dust/fume/gas/mist/vapors/spray   |
| P264      | Wash thoroughly after handling.   |
| P270      | Do not eat, drink or smoke when using this product.   |
| P272      | Contaminated work clothing must not be allowed out of the workplace.                                  |
| P280      | Wear protective gloves/protective clothing/eye protection/face protection.                            |
| P284      | [In case of inadequate ventilation] wear respiratory protection.                                      |
| P301+P312 | If swallowed: Call a poison center/doctor if you feel unwell.   |
| P330      | Rinse mouth.  |
| P302+P352 | If on skin: Wash with plenty of water.  |
| P304+P341 | If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. |
| P308+P313 | If exposed or concerned: Get medical advice/attention.  |
| P321      | Specific treatment (see on this label).   |
| P333+P313 | If skin irritation or rash occurs: Get medical advice/attention.                                      |
| P342+P311 | If experiencing respiratory symptoms: Call a poison center/doctor.                                    |
| P363      | Wash contaminated clothing before reuse.  |
| P405      | Store locked up.  |
| P501      | Dispose of contents/container in accordance with local/regional/national/international regulations.   |

## Classification system:

### NFPA rating (scale 0 - 4)

|   |  |
|---|--|
|  | Health = 1<br>Fire = 0<br>Reactivity = 0 |
|---|--|

### HMIS-ratings (scale 0 - 4)

|   |   |
|---|---|
|  | Health = *1<br>Fire = 0<br>Reactivity = 0 |
|---|---|

## 2.3. Other hazards:

Results of PBT and vPvB assessment:

The substance is not considered PBT/vPvB according to criteria in Annex XIII.

### 3. SECTION: Composition/Information on ingredients.

#### 3.1. Substances:

##### **Chemical characterization (substance):**

|              |                                       |
|--------------|---------------------------------------|
| CAS:         | 73368-74-8                            |
| Description: | Penicillin V (calcium dihydrate salt) |
| UNII:        | JJZ37N4VOX                            |

#### 3.2. Mixtures:

N/A

### 4. SECTION: First aid measures.

#### 4.1. Description of first aid measures:

##### **General information:**

Symptoms of poisoning may even occur after several hours; therefore, medical observation for at least 48 hours after the accident.

##### **After eye contact:**

Rinse opened eye for several minutes under running water.

##### **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

##### **After swallowing:**

Immediately call a doctor.

##### **After inhalation:**

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably inside position for transportation.

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

May cause anemia, cough, CNS depression, drowsiness, headache, heart damage, lassitude (weakness, exhaustion), liver damage, narcosis, reproductive effects, teratogenic effects.  
No further relevant information available.

#### 4.3. Indication of any immediate medical attention and special treatment needed:

No further relevant information available

##### **Antidote information:**

No specific antidote available.

### 5. SECTION: Firefighting media.

#### 5.1. Extinguishing media:

Use fire fighting measures that suit the environment.  
A solid water stream may be inefficient.

**5.2. Special hazards arising from the substance or mixture:**

No further relevant information available.

**5.3. Advice for firefighters:**

No special measures required.

**6. SECTION: Accidental release measures.**

**6.1. Personal precautions, protective equipment, and emergency response:**

Not required.

**6.2. Environmental precautions:**

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

**6.3. Methods and materials for containment and cleaning up:**

Ensure adequate ventilation. Use personal protective equipment. Should not be released into the environment. Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Disposal must be made according to official regulations.

**6.4. References to other sections:**

PAC-1: Substance is not listed.

PAC-2: Substance is not listed.

PAC-3: Substance is not listed.

**7. SECTION: Handling and storage.**

**7.1. Precautions for safe handling:**

Usual safety precautions should be observed to ensure safe handling.  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of dust.  
Avoid contact with eyes and skin.  
Do not inhale dust/smoke/mist.  
Wash hands before breaks and at the end of work.  
Remove and wash contaminated clothing before re-use.  
Smoking, eating and drinking should be prohibited in application area.

**7.2. Conditions for safe storage, including any incompatibilities:**

Store only in the original container tightly sealed.  
Keep cool, dry, ventilated storage and closed containers.  
Protect from light.  
Keep out of sunlight.  
Keep away from heat.  
Water sensitive materials.  
Protect from moisture.

### 7.3. Specific end uses:

No further relevant information available.

## 8. SECTION: Exposure control / personal protection.

### 8.1. Control parameters:

#### Exposure limits and guidelines

Not required.

The lists that were valid during the creation were used as basis.

### 8.2. Exposure controls:

#### Appropriate engineering controls:

Use engineering controls to reduce air contamination

#### Personal protective equipment:

##### General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work

##### Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

##### Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

##### Material of gloves:

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

##### 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.

##### Eye and face protection:

Not required.

## 9. SECTION: Physical and chemical properties.

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

|                            |   |
|----------------------------|---|
| <b>Physical state:</b>     | Solid.  |
| <b>Color:</b>              | Not determined.   |
| <b>Odor:</b>               | Characteristic.   |
| <b>Odor threshold:</b>     | Not determined.   |
| <b>Structural Formula:</b> | C <sub>32</sub> H <sub>40</sub> N <sub>4</sub> O <sub>12</sub> S <sub>2</sub> • Ca • 2 H <sub>2</sub> O |
| <b>Molecular Weight:</b>   | 812.9 g/mol   |
| <b>pH-value:</b>           | Not applicable.   |

|  |   |
|--|---|
| Melting point/Melting range:             | Undetermined.                                 |
| Boiling point/Boiling range:             | Undetermined.                                 |
| Flash point:                             | Not applicable.                               |
| Flammability (solid, gaseous):           | Product is not flammable.                     |
| Decomposition temperature:               | Not determined.                               |
| Auto igniting:                           | Not determined.                               |
| Danger of explosion:                     | Product does not present an explosion hazard. |
| Explosion limits: Lower:                 | Not determined.                               |
| Upper:                                   | Not determined.                               |
| Vapor pressure:                          | Not applicable.                               |
| Density:                                 | Not determined.                               |
| Relative density:                        | Not determined.                               |
| Vapor density:                           | Not applicable.                               |
| Evaporation rate:                        | Not applicable.                               |
| Solubility in / Miscibility with Water:  | Not determined.                               |
| Partition coefficient (n-octanol/water): | Not determined.                               |
| Viscosity: Dynamic:                      | Not applicable.                               |
| Kinematic:                               | Not applicable.                               |
| Solubility:                              | Not applicable.                               |

## 9.2. Other information:

No further relevant information available.

## 10. SECTION: Stability and reactivity.

### 10.1. Reactivity:

No further relevant information available.

### 10.2. Chemical stability:

Stable at normal temperatures and pressures.

### 10.3. Possibility of hazardous reactions:

No dangerous reactions known.

### 10.4. Conditions to avoid:

No further relevant information available.

### 10.5. Incompatible materials:

Strong oxidizing agents.

### 10.6. Hazardous decomposition products:

Carbon dioxide, carbon monoxide, nitrogen oxides, nitrogen oxides, sulfur oxides.

## 11. SECTION: Toxicological information.

|                              |                 |
|------------------------------|-----------------|
| RTECS Number:                | Not applicable. |
| Acute dermal LD50:           | Not determined. |
| Acute oral LD50:             | Not determined. |
| Acute intraperitoneal LD 50: | Not determined. |
| Acute subcutaneous LD50:     | Not determined. |
| Acute intravenous LD50:      | Not determined. |

|                               |  |
|-------------------------------|--|
| <b>Acute inhalation LC50:</b> | Not determined.  |
| <b>Eye effects:</b>           | No irritating effect.  |
| <b>Skin effects:</b>          | No irritating effect.  |
| <b>Sensitization:</b>         | Sensitization possible through inhalation.<br>Sensitization possible through skin contact. |
| <b>Listed by IARC:</b>        | No   |
| <b>Listed by NTP:</b>         | No   |
| <b>Listed by OSHA:</b>        | No   |

## **12. SECTION: Ecological information.**

### **12.1. Toxicity:**

#### **Aquatic toxicity:**

No further relevant information available.

### **12.2. Persistence and degradability:**

No applicable information found.

### **12.3. Bioaccumulative potential:**

No applicable information found.

### **12.4. Mobility in soil:**

No applicable information found.

#### **Additional ecological information:**

Water hazard class 1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

### **12.5. Results of PBT and vPvB assessment:**

The substance is not considered PBT/vPvB according to criteria in Annex XIII.

### **12.6. Other adverse effects:**

No applicable information found.

## **13. SECTION: Disposal consideration.**

### **13.1. Waste treatment methods:**

#### **Recommendation:**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

#### **Uncleaned packagings:**

Recommendation: Disposal must be made according to official regulations.



## 14. SECTION: Transport information.

### 14.1. UN number:

Not regulated.

### 14.2. UN proper shipping name:

Not regulated.

### 14.3. Transport hazard class(es):

Not regulated.

### 14.4. Packing group:

Not regulated.

### 14.5. Environmental hazards:

Not applicable.

### 14.6. Special precautions for user:

Not applicable.

### 14.7. Transport in bulk according to Annex II MARPOL 73/78 and the IBC Code:

Not applicable.

## 15. SECTION: Regulatory information.

### 15.1. Safety, health and environmental regulation/legislation specific for the substance or mixture:

No further relevant information available.

Sara

#### Section 355 (extremely hazardous substances):

Substance is not listed.

#### Section 313 (Specific toxic chemical listings):

Substance is not listed.

#### TSCA (Toxic Substances Control Act):

ACTIVE

#### Hazardous Air Pollutants:

Substance is not listed.

#### Proposition 65

##### Chemicals known to cause cancer:

Substance is not listed.

##### Chemicals known to cause reproductive toxicity for females:

Substance is not listed.

##### Chemicals known to cause reproductive toxicity for males:

Substance is not listed.

**Chemicals known to cause developmental toxicity:**

Substance is not listed.

**Carcinogenic categories**

**EPA (Environmental Protection Agency)**

Substance is not listed.

**TLV (Threshold Limit Value)**

Substance is not listed.

**NIOSH-Ca (National Institute for Occupational Safety and Health)**

Substance is not listed.

**Chemical safety assessment:**

A Chemical Safety Assessment has not been carried out.

**15.2. Chemical safety assessment:**

A Chemical Safety Assessment has not been carried out.

**16. SECTION: Other information.**

|                             |   |
|-----------------------------|---|
| <b>Reason for issue:</b>    | EC regulation, REACH and CLP  |
| <b>Contact Information:</b> | See Section 1   |
| <b>Revision summary:</b>    | This document has undergone significant changes and should be reviewed in its entirety. |

|                            | <b>HMIS RATING</b> | <b>NFPA RATING</b> |
|----------------------------|--------------------|--------------------|
| <b>Health</b>              | ND                 | ND                 |
| <b>Flammability</b>        | ND                 | ND                 |
| <b>Physical hazard</b>     | ND                 | ND                 |
| <b>Personal protection</b> | ND                 | ND                 |
| <b>Incompatibilities</b>   | ND                 | ND                 |

**Data sources:**

Micromedex DrugDex; Mosby's Drug Consult; Physicians Desk Reference; RTECS, PubChem, Kucers' The use of antibiotics, ECHA.

**Disclaimer:**

Information given herein is offered in good faith as accurate, but without guarantee. Conditions of use and suitability of the product for particular uses are beyond our control; all risks of use of the product are therefore assumed by the user. Nothing is intended as a recommendation for uses that infringe valid patents or as extending license under valid patents. Appropriate warnings and safe handling procedures should be provided to handlers and users.

**Glossary:**

- ACGIH – American Conference of Governmental Hygienists
- AIHA – American Industrial Hygiene Association
- BEI – Biological Exposure Index
- CAS – Chemical Abstract Service Registry Number
- CSR – Chemical Safety Report
- CERCLA – Comprehensive Environmental Response Compensation and Liability Act of 1989
- CHEMTREC – Chemical Transportation Emergency Center

DOT – Department of Transportation (USA)  
EC – European Community  
EINECS – European Inventory of Existing Chemical Substances  
ELINCS - European List of New Chemical Substances  
EPA – Environmental Protection Agency  
FDA – United States Food and Drug Administration  
HEPA- High Efficiency Particulate Air (Filter)  
HMIS – Hazardous Material Information System  
IARC- International Agency on Research for Cancer  
ICAO/IATA – International Civil Aviation Organization/International Air Transport Association  
IMO – International Maritime Organization  
LEL – Lower Explosive Limit  
MSDS – Material Safety Data Sheet  
MSHA – Mine Safety and Health Administration  
NA – Not Applicable  
NADA – New Animal Drug Application  
NAIF – No Applicable Information Found  
NCI – National Cancer Institute  
ND – Not Determined  
NFPA – National Fire Protection Association  
NIOSH – National Institute for Occupational Health and Safety  
NL – Not Listed  
NOS – Not Otherwise Specified  
NTP – National Toxicology Program  
OEL – Occupational Exposure Limit  
OSHA – Occupational Safety and Health Administration  
PEL – Permissible Exposure Limit (USA)  
RCRA – Resource Conservation and Recovery Act  
RQ – Reportable Quantity  
RTECS – Registry of Toxic Effects of Chemical Substances  
SARA – Superfund Amendments and Reauthorization Act  
STEL – Short Term Exposure Limit  
TLV – Threshold Limit Value  
TPQ – Threshold Planning Quantity  
TSCA – Toxic Substances Control Act  
TWA – Time Weighted Average  
UEL – Upper Explosive Limit  
UN – United Nations  
WEEL – Workplace Environmental Exposure Level (USA - AIHA)