

SAFETY DATA SHEET

Revision date: February 2016

Version: 1

Page 1 of 8

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier**Material Name:** Penicillin G potassium**Trade Name:** R-Pen®
Chemical Family: Penicillin**Relevant Identified Uses of the Substance or Mixture and Uses Advised Against****Intended Use:** Veterinary antibiotic agent
Restrictions on Use: Not for human use**Manufacturer/Supplier:**Huvepharma Inc.
612 S 28th Street
Van Buren, AR 72956Huvepharma, Inc.
525 Westpark Drive, Suite 230
Peachtree City, GA 30269
Telephone: 1-770-486-7212**Emergency telephone number:** 1-877-994-4883
Contact e-mail: customerservice@huvepharma.us

2. HAZARDS IDENTIFICATION

Appearance: White, granular powder in pre-measured, single-dose pouches**Classification of the Substance or Mixture****GHS - Classification**Respiratory Sensitization: Category 1
Skin Sensitization: Category 1**US OSHA Specific - Classification****Physical Hazard:** Combustible Dust**EU Classification:**

EU Indication of danger: Harmful

EU Symbol: Xn

EU Risk Phrases:
R42/43 - May cause sensitization by inhalation and skin contact.**Label Elements****Signal Word:** Danger**Hazard Statements:** H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H317 - May cause an allergic skin reaction
May form combustible dust concentrations in air

SAFETY DATA SHEET

Material Name: Penicillin G potassium
Revision date: February 2016

Page 2 of 8
Version: 1

Precautionary Statements:

- P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
- P240 - Ground/Bond container and receiving equipment
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
- P285 - In case of inadequate ventilation wear respiratory protection
- P272 - Contaminated work clothing should not be allowed out of the workplace
- P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
- P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician
- P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
- P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
- P362 - Take off contaminated clothing and wash before reuse
- P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards
Short Term:

Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients. Individuals who are allergic to penicillin antibiotics could have allergic reaction, possibly severe. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted. May cause eye irritation. Signs and symptoms might include redness, swelling, blurred vision or pain.

Known Clinical Effects:

May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug.

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Penicillin G potassium	113-98-4	204-038-0	Xn;R42/43	Resp. Sens.1 (H334) Skin Sens.1 (H317)	100

SAFETY DATA SHEET

Material Name: Penicillin G potassium
Revision date: February 2016

Page 3 of 8
Version: 1

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

- Eye Contact:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
- Skin Contact:** Remove contaminated clothing and shoes and thoroughly wash skin with soap or mild detergent and water. If irritation occurs or persists, get medical attention. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately. Seek immediate medical assistance in case of known or possible overexposure to this material or with symptoms including chest pain, difficulty breathing, loss of consciousness or other adverse effects which may be delayed.

Most Important Symptoms and Effects, Both Acute and Delayed

- Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
- Medical Conditions Aggravated by Exposure:** Breathing dust may worsen asthma symptoms. People allergic to penicillins may exhibit cross reaction sensitivity.

Indication of the Immediate Medical Attention and Special Treatment Needed

- Notes to Physician:** None

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

- Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.
- Fire / Explosion Hazards:** During processing, dust may form explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Avoid dust formation.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

SAFETY DATA SHEET

Material Name: Penicillin G potassium
Revision date: February 2016

Page 4 of 8
Version: 1

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Contain the source of the spill if it is safe to do so. Collect spilled material by a method that controls dust generation. Clean spill area thoroughly.

Additional Consideration for Large Spills: Avoid generating airborne dust. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal. Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Minimize dust generation and accumulation. Use with adequate ventilation. When handling, use appropriate personal protective equipment (see Section 8). Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Keep container tightly closed when not in use. Store out of direct sunlight in a well ventilated area at room temperature. Keep away from heat, sparks, flame, and other sources of ignition.

Storage Temperature: 20-25°C

Incompatible Materials: Acids, bases, and oxidizers

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Penicillin G potassium

Huvepharma OEB

OEB 2 - Sensitizer (control exposure to the range of 100ug/m³ to < 1000ug/m³, provide additional precautions to protect from skin contact)

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels within the OEB range. General room ventilation is adequate unless the process generates dust, mist or fumes.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Wear impervious gloves if skin contact is possible.

Eyes: Safety glasses or goggles

Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

SAFETY DATA SHEET

Material Name: Penicillin G potassium
Revision date: February 2016

Page 5 of 8
Version: 1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection: If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Powder	Color:	White
Odor:	Odorless	Odor Threshold:	No data available.
Molecular Formula:	C ₁₆ H ₁₈ N ₂ O ₄ S.K	Molecular Weight:	372.48

Solvent Solubility:	Soluble: Ethanol, Methanol, Glycerol
Water Solubility:	Highly soluble: Water
pH:	5 - 7.5 (3% aqueous solution)
Melting/Freezing Point (°C):	214 - 217C (417.2 - 422.6F)
Boiling Point (°C):	No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)	
Penicillin G potassium	1.83
Decomposition Temperature (°C):	No data available.

Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	Negligible
Vapor Density (g/ml):	No data available
Relative Density:	No data available
Specific Gravity:	0.4
Viscosity:	No data available

Flammability:

Autoignition Temperature (Solid) (°C):	>210C (>410F)
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Keep away from heat and other sources of ignition, including electrostatic discharge. Avoid dispersion as a dust cloud. Dust may form explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	Acids, bases, and oxidizers
Hazardous Decomposition Products:	This material will decompose at 214 - 217°C. Thermal decomposition products include oxides of carbon, nitrogen, and sulfur.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

SAFETY DATA SHEET

Material Name: Penicillin G potassium
Revision date: February 2016

Page 6 of 8
Version: 1

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of various forms of the active ingredient. The toxicities of the two materials can be expected to be similar. Toxicological properties have not been thoroughly investigated. Routes of exposure: eye contact, skin contact, inhalation

Acute Toxicity: (Species, Route, End Point, Dose)

Penicillin G potassium

Mouse Oral LD50 6257 mg/kg
Rat Oral LD50 8900mg/kg
Rabbit Oral LD50 5848mg/kg

Inhalation Acute Toxicity

Inhalation of dust may cause irritation of the respiratory tract and mucous membranes and allergic reactions in susceptible individuals.

Irritation / Sensitization Comments: May cause eye irritation.

Skin Irritation / Sensitization

Penicillins are known to cause contact dermatitis and allergic reactions in sensitive individuals.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Penicillin V Potassium

14 Day(s) Rat Oral 2400 mg/kg/day NOAEL None identified
14 Day(s) Mouse Oral 2400 mg/kg/day NOAEL None identified
13 Week(s) Rat Oral 750 mg/kg/day LOEL Gastrointestinal system
13 Week(s) Mouse Oral 250 mg/kg/day LOEL Gastrointestinal system

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Penicillin V Potassium

In Vitro Bacterial Mutagenicity (Ames) Negative
In Vitro Cell Transformation Assay Mouse Lymphoma Positive with activation
Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Positive without activation
Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Negative with activation

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Penicillin V Potassium

2 Year(s) Rat Oral 1000 mg/kg/day NOEL Not carcinogenic
2 Year(s) Mouse Oral 1000 mg/kg/day NOEL Not carcinogenic

Carcinogen Status:

Not listed as a carcinogen by IARC, NTP or US OSHA.

SAFETY DATA SHEET

Material Name: Penicillin G potassium
Revision date: February 2016

Page 7 of 8
Version: 1

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Penicillin G potassium

Daphnia magna (Water Flea) LC50 48 Hours > 1000 mg/L

Nitzschia fonticola (Diatom) LC50 630 Days 2000 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Persistence and Degradability: No data available

Bio-accumulative Potential:

Penicillin G potassium 1.83

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Should not be released into the environment. Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

SAFETY DATA SHEET

Material Name: Penicillin G potassium
Revision date: February 2016

Page 8 of 8
Version: 1

15. REGULATORY INFORMATION

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.



Penicillin G potassium

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

EU EINECS/ELINCS List

204-038-0

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Xn - Harmful

R42/43 - May cause sensitization by inhalation and skin contact.

Data Sources:

The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision:

Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 9 - Physical and Chemical Properties. Updated Section 11 - Toxicology Information.

Prepared by:

Toxicology and Hazard Communication
Huvepharma Global Risk Management

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End of Safety Data Sheet