



HANGZHOU DINGYAN CHEM CO., LTD

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MATERIAL SAFETY DATA SHEET

1 Identification

Material Name: Penicillin V Potassium

English Name: Phenoxymethylpenicillin Potassium

Chemical Name: 4-Thia-1-azabicyclo[3.2.0] heptane-2-carboxylic acid,
3,3-dimethyl-7-oxo-[6-(phenoxyacetyl) amino]-, mono potassium salt, [2S-(2a,5a,6B)]-

CAS Number: 132-98-9

Manufacturer: NORTH CHINA PHARMACEUTICAL CO., LTD

Address: No.388, Heping East Road, Shijiazhuang, Hebei, China

Post Code: 050015

Manufacturer's website: www.ncpc.com

Emergency Phone: 0086-311-5992619

2 Ingredient and Characters

Components: Penicillin V Potassium

Assay: 95.5% ~ 100.5%

Characters: A white, crystalline or crystalline powder

3 Health Hazard Information

The usual dosage recommendation for adults:

Streptococcal Infections: 125~250mg every 6 to 8 hours for 10 days.

Peumococcal Infections: 250~500mg every 6 to 8 hours until the patient has been a febrile for at least 2 days.

Staphylococcal Infections、Fusospirochetosis (Vincent's Infection of the Oropharynx): 250~500mg every 6 to 8 hours.

For prophylaxis against bacterial endocarditis and when undergoing dental procedures or surgical procedures of the upper respiratory tract, the usual adult dosage is 2g of penicillin

V (1g for children less than 27kg) 1 hour before the procedure and the 1g(500mg for children less than 27kg) 6hours later.

Adverse Effects:

1. The most common reactions to oral penicillin are nausea, vomiting, epigastric distress, diarrhea, and black, hairy tongue.
2. The hypersensitivity reactions noted are skin eruptions, urticaria, reactions resembling serum sickness, including, fever, edema, and, laryngeal edema and acidophil increase.
3. Bi-layer infections: Taking a product long-term and in a large amount can be caused golden yellow staphylococcus against penicillin,
4. Hemolytic anemia, leukopenia, thrombocytopenia, neuropathy, and nephropathy are infrequent

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reactions.

Taboo:

Those who, have reports of individuals with a history of penicillin hypersensitivity and have experienced severe reactions when treated with cephalosporins, should not use penicillin v potassium.

4 First Aid Measures

Overdose Treatment: Once persons developing serious hypersensitivity, must be rescue on the spot, and should be given injections of 1% of the adrenaline (0.5-1ml). Dilute sodium chloride liquid and 5% of the glucose may be useful in case of necessity. The person who stops heartbeat, the adrenaline can be made and injected in the heart. And at the same time, the patient can be given heavy dose of cortin through a vein, and blood. If the overdose occurred, penicillin v potassium should be stopped and give adequate treatment to the patient. And the hemodialysis can remove the pencicillin.

5 Explosive and Firefighting Measures

Upper Flammable Limit: No

Lower Flammable Limit: No

Auto-Ignition Temperature: No

Extinguisher Media: Water, carbon dioxide, dry chemical and foam.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use automatic breathing equipment and protective clothing.

6 Protection Measures

States Standard: The lustration grade of air is 300,000 grades. Lustration area $\geq 0.5\mu\text{m}$ The quantity of dust/ $\text{m}^3 \leq 10500000$ The times of changing air is 12 per hour. The difference of air pressure ranking different rooms $\geq 5\text{pa}$, The difference of lustration area and outside of the room $\geq 10\text{pa}$.

Detecting Measures: laser air particle counter and differential pressure meter

Process Control: The production process should be tight, and the supplies entering the clean area should be washed, and disinfected. Other producing areas should keep clean, be neat, and have no incidental. There are no seeper, and the doors, windows, glasses, walls and ceiling is clean and intact.

Personnel and Respiratory Protection: Entering the clean area, persons should wear adequate woke clothes, shoes, hats and masks.

Hands Protection: Touching the raw material, rubber gloves should be required.

Others: Eating in work place is strictly forbidden. After work, the work clothes should be changed. The physical examination before working and in working is very necessary.

7 Laws and Regulations

Pharmaceutical Administration Law of the People's Republic of China The National People's Congress issued on February 28, 2001, and implemented from December 1, 2001.

Implementing regulations of the Pharmaceutical Administration Law of the People's Republic of China The state council issued on August 4, 2002, and implemented from September 15, 2002.

Safety in Production Law of the People's Republic of China The National People's Congress issued on June 29, 2002, and implemented from November 1, 2002.

Safe Management Rule of Dangerous Chemicals The State Council issued on January 26, 2002, and implemented from March 15, 2003.

8 Spill Measures

(1). Spill Response and Disposal

Methods: When the drum and bag was damaged, wipe up spillage or collect respiratory using a high efficiency vacuum cleaner. Place spillage in appropriately labeled container for disposal. Flush with copious quantities of buck.

Disposals: The package materials touching the raw materials directly can be cleaned by drinking water, then can be used dually or

(2). Exposure and Personal Protection

Ventilation: No special ventilation requirements.

Eye Protection: No special requirements.

Body Protection: Work clothes, shoes, hats to dissipate the static electricity.

Hand Protection: Protective gloves.

Respiratory Protection: When contact with the powder, the worker should wear filtrating mask.

Others: Eating in work place is strictly forbidden. After work, the work clothes should be changed.

The physical examination before working and in working is very necessary. The person who has contagion and dermatosis is forbidden to work in this area.

9 Storage and Transporting Measures

Stored in a cool, dry and clean storehouse, this product should be far away from tinder and heat source and not be affected by damp and rain, and also preserved with other chemical product, and non-penicillin pharmaceuticals separately. No transporting and storing with acid and alkaline products. This product should be moved slightly. Inverting, rain, dirt, mouse, insect and lose was forbidden. Stocking should be in accordance with the requirements. And also protecting label from damaging is very necessary. When check before acceptance, we should pay more attention to the material name, batch number, date and use the earliest product. And also this material does not fit for transporting in a rainy day.

10 Transporting and Storing Information

Dangerous Mark: Non-dangerous chemical product.

Packing: bi-layer plastic bags, outside paper drum and bag.

11 Environment Information

This product may cause to water and soil pollution.

12 Refuse Disposal

It is a dangerous refuse, and stored and transported in accordance with the requirements of dangerous refuse. And the last disposal method is burning.

13 Physical and Chemical Properties

Characters: White crystalline or white crystalline powder, smell-less or slightly smell-less. Practically soluble in water, insoluble in chloroform, alcohol and olefin liquor.

Identification: 1) The infrared collection of illustrative plates of sample is contract with the compared product.

2) The color of the sample is similar with that of kainite reaction.

Specific optical rotation: $+215^{\circ} \sim +230^{\circ}$

PH Value: 5.5~7.5

Absorbance 306nm: ≤ 0.33

274nm: ≥ 0.5

Phenoxyacetic Acid: $\leq 0.5\%$

Related Substance: Meet the requirement

4-Hydroxyphenoxyethylpenicillin potassium: $\leq 4.0\%$

Water: $\leq 0.8\%$

The quantity of mildew and barm: ≤ 100 entries/g

The color of the liquor ≤ 2

Macromolecule impurity $\leq 0.1\%$

Eyewinker ≤ 6 entries/g

14 Stability

Stability: stable under the requirement of storage.

Decomposition Products: When heated to decomposition material emits toxic fumes of NO_x, K₂O and SO_x. Emits toxic fumes under fire conditions.

15 Toxicological Information

The neuritis may happen in the penicillin skin injecting area. But this situation is infrequent. And must make test before injecting. The concentration of the medicine is 500 unit/ml.