



Safety Data Sheet

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

GHS product identifier

Product name: K-Phos Neutral

Other mean of identification

Product code(s): 0486-1125-01, 0486-1125-05

UN-Number: NA

Synonyms: NA

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical product used for use as a phosphorus supplement.

Uses advised against: Do not use except as prescribed.

Supplier address/information

Beach Pharmaceuticals
Division of Beach Products Inc.
3010 W de Leon St
Tampa, FL 33609
813-839-6565

Emergency telephone number

CHEMTREC 800.424.9300

2. Hazards Identification

Classification This product is a mixture and is a pharmaceutical product. It is considered non-Hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

Chemical Family: Mixture

Statement of Hazard: Tablet is intended for oral consumption under the guidance of a physician. Product is not likely to be harmful taken as prescribed by a physician.

Additional Hazard Information

Short term: No data available

Long term: No data available

Known Clinical Effects:

Therapeutic use of this substance may result in gastrointestinal upset (diarrhea, nausea, stomach pain and vomiting) and joint pain (possible phosphate-induced osteomalacia). Adverse effects that may be observed with potassium or sodium administration: headache, dizziness, mental confusion, seizures, weakness or heaviness of legs, unusual tiredness or weakness, muscle cramps, numbness, tingling, pain, or weakness of hands or feet; numbness or tingling around lips; fast or irregular heartbeat; swelling of feet or lower legs; unusual weight gain; low urine output, and unusual thirst.

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EU Indication of danger: Not classified.

Emergency Overview

Seek medical attention in case of accidental exposure or overdose. The product is generally safe when used as prescribed.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential of exposure in your workplace.

Precautionary Statements

General advice: Seek medical attention in case of accidental exposure or overdose.

Eyes: No issues likely.

Skin Contact: No issues likely.

Inhalation: Not intended for inhalation.

Ingestion: Generally safe at recommended doses. In case of overdose, seek medical attention immediately.

Storage: There are no special storage conditions for safety. For product integrity, store under conditions specified on the label.

Disposal: Dispose of in accordance with applicable laws and regulations.

3. Composition/Information on ingredients

Chemical Name	CAS-No	mg/tablet	Trade Secret
Potassium Phosphate Monobasic	7778-77-0	155 mg/tablet	
Monobasic Sodium Phosphate, Anhydrous	7558-80-7	113 mg/tablet	
Dibasic Sodium Phosphate, Anhydrous	7558-79-4	852 mg/tablet	
Povidone	9003-39-8		X
Isopropyl Alcohol	67-63-0		X
Lactose Monohydrate	64044-51-5		X
Sodium Starch Glycolate	9063-38-1		X
Magnesium Stearate	557-04-0		X
Opadry White Coating	Mixture		X

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4. First aid measure

Description of necessary first-aid measures

Eye contact: No treatment normally would be required.

Skin contact: No treatment normally would be required.

Inhalation: No treatment normally would be required.

Overdosage or accidental ingestion: Do not induce vomiting. Contact medical personnel or poison control center.

Most important symptoms/effects, acute and delayed

No data available

Indication of immediate medical attention and special treatment needed, if necessary

NA

Notes to Physician

NA

5. Fire-fighting measures

Suitable extinguishing media:

Use carbon dioxide, dry chemical or water spray.

Specific hazards arising from the chemical

None

Explosion data:

Not applicable

Protective equipment and precautions for firefighters

During all firefighting activities, wear appropriate protective for 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.

Environmental precautions

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

Methods and materials for containment and cleaning up

- Methods for containment:
- Methods for cleaning up:

No special handling required.

Sweep up spilled material and dispose of in accordance with applicable local, state and federal regulations.



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7. Handling and storage

Precautions for safe handling

Handling: No special handling required for hazard control under conditions of normal product use.

Conditions for safe storage, including any incompatibilities

Storage: No special storage required for hazard control. For product protection, follow storage recommendations on the case label, primary product label and insert.

Incompatible products: Not applicable.

8. Exposure controls/personal protection

Control parameters

Exposure guidelines: The exposure guidelines listed below are for the individual components and not the product itself.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Potassium Phosphate Monobasic	Not Available	Not Available	Not Available
Monobasic Sodium Phosphate, Anhydrous	Not Available	Not Available	Not Available
Dibasic Sodium Phosphate, Anhydrous	Not Available	Not Available	Not Available
Povidone	Not Available	Not Available	Not Available
Isopropyl Alcohol	200 ppm	400ppm TWA	400 ppm
Lactose Monohydrate	Not Available	Not Available	Not Available
Sodium Starch Glycolate	Not Available	Not Available	Not Available
Magnesium Stearate	10 mg/m ³ TWA	Not Available	Not Available
Opadry White Coating	Not Available	Not Available	Not Available

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Appropriate engineering controls

Engineering measures: Engineering controls should be used to limit exposure.

Individual protection measures, such as personal protective equipment

Eye/face protection: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin and body protection: Impervious gloves and protective clothing are recommended if skin contact with drug product is possible and for bulk processing operations

Respiratory protection: Not required under normal use of the product. If the applicable PEL (Permissible Exposure Limit) is exceeded use an appropriate respirator.

Hygiene measures: Wash hands thoroughly after use.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state: White coated, capsule shaped tablet, with logo BEACH on one side and 11/25 on the other side.

Odor: None

Property	Values	Remarks/Method
pH	Not applicable	
Melting point/range	Not applicable	
Boiling point/boiling range	Not applicable	
Flash point	Not applicable	
Evaporation rate	Not applicable	
Flammability (solid, gas)	Not applicable	
Flammability limits in air	Not applicable	
-upper flammability limit	Not applicable	
-lower flammability limit	Not applicable	
Vapor pressure	Not applicable	
Vapor density	Not applicable	
Specific gravity	Not applicable	
Water solubility	Not applicable	
Solubility in other solvents	Not applicable	

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Property	Values	Remarks/Method
Partition coefficient: n-octanol/water	Not applicable	
Autoignition temperature	Not applicable	
Decomposition temperature	Not applicable	
Viscosity	Not applicable	
Flammable properties	Not applicable	
Explosive properties	Not applicable	
Oxidizing properties	Not applicable	

Other information

VOC content (%): None

10. Stability and reactivity

Reactivity Stable at normal conditions

Chemical stability Stable at normal conditions

Possibility of hazardous reactions Stable at normal conditions

Conditions to avoid None known

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

Hazardous decomposition products None known

11. Toxicological information

Information on likely routes of exposure

Product information:

- Inhalation: Not Available
- Eye contact: Not Available
- Skin contact: Not Available
- Ingestion: Not Available

The information included in this section, below, describes the potential hazards of the individual ingredients.

Chemical Name	LD50 oral	LD50 dermal	LC50 inhalation
Potassium Phosphate Monobasic	>2000 mg/kg Rat	>4640 mg/kg Rabbit	Not Available
Monobasic Sodium Phosphate, Anhydrous	8290 mg/kg Rat	Not Available	Not Available
Dibasic Sodium Phosphate, Anhydrous	17000 mg/kg Rat	Not Available	Not Available
Povidone	40000 mg/kg Mouse	Not Available	Not Available
Isopropyl Alcohol	5045 mg/kg Rat	128000 mg/kg Rabbit	16000 ppm 8 hr. Rat
Lactose Monohydrate	10000 mg/kg Rat	Not Available	Not Available
Sodium Starch Glycolate	Not Available	Not Available	Not Available
Magnesium Stearate	Not Available	Not Available	Not Available
Opadry White coating	Not Available	Not Available	Not Available

Symptoms related to the physical, chemical and toxicological characteristics

No data available

Delayed and immediate effects and also chronic effects from short and long term exposure

- Sensitization: No data available
- Mutagenic effects: No data available
- Carcinogenicity: No data available
- Reproductive toxicity: No data available
- STOT – single exposure: No data available
- STOT – repeated exposure: No data available
- Aspiration hazard: No data available

Numerical measures of toxicity – product

No data available

12. Ecological information

Ecotoxicity:

Environmental properties have not been thoroughly evaluated for the product. Releases to the environment should be avoided.

Persistence and Degradability

No data available

Bioaccumulation

No data available

Other adverse effects:

No data available

The following table includes data for the individual components.

Chemical Name	Toxicity to algae	Toxicity to fish	Toxicity to micro-organisms	Daphnia Magna (water flea)
Potassium Phosphate Monobasic	Not Available	Not Available	Not Available	Not Available
Monobasic Sodium Phosphate, Anhydrous	Not Available	Not Available	Not Available	Not Available
Dibasic Sodium Phosphate, Anhydrous	Not Available	Not Available	Not Available	Not Available
Povidone	Not Available	Not Available	Not Available	Not Available
Isopropyl Alcohol	> 2000 mg/L 72 hr.	9640 mg/L 96 hr. <i>Pimephales promelas</i>	Not Available	5102 mg/L 24 hrs.
Lactose Monohydrate	Not Available	Not Available	Not Available	Not Available
Sodium Starch Glycolate	Not Available	Not Available	Not Available	Not Available
Magnesium Stearate	Not Available	Not Available	Not Available	Not Available
Opadry White Coating	Not Available	Not Available	Not Available	Not Available

13. Disposal considerations

Waste disposal methods

Dispose of waste in accordance with all federal, state and local regulations.

Contaminated packaging

Dispose of waste in accordance with all federal, state and local regulations.

14. Transport information

Notes:

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

15. Regulatory information

International inventories

TSCA:

United States Toxic Substances Control Act 8(b) inventory not applicable to product, but the following ingredients are listed on TASC inventories: Potassium Phosphate Monobasic, Sodium Phosphate Dibasic, Monobasic Sodium Phosphate, Anhydrous, Povidone, Isopropyl Alcohol, Lactose Monohydrate, Sodom Starch Glycolate, and Magnesium Stearate

EINECS:

Potassium Phosphate Monobasic, Sodium Phosphate Dibasic, Monobasic Sodium Phosphate, Anhydrous, Povidone, Isopropyl Alcohol, Lactose Monohydrate, Sodom Starch Glycolate, and Magnesium Stearate are listed on the inventory.



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U.S. Federal regulations:
Not Applicable

SARA 311/312 Hazard categories:

- Isopropyl Alcohol is listed as a fire hazard, acute health hazard and chronic health hazard.
- Dibasic Sodium Phosphate, Anhydrous is listed under SARA 311/3/12 with a threshold quantity if 500 lbs.
- Magnesium Stearate is listed as an acute health hazard.

Clean Water Act:

- This product **does not** contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).
- Sodium Phosphate Dibasic is listed under 40 CFR 117.3 with a reportable quantity of 5000 lbs.

CERCLA:

Sodium Phosphate dibasic, Anhydrous is listed under CERCLA.

California Proposition 65:

This product does contain Magnesium Stearate which is listed in Proposition 65 as causing cancer, birth defects or reproductive harm.

U.S. state Right-to-Know regulations

“X” designates that the ingredients are listed on the state Right-to-Know list

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Potassium Phosphate Monobasic	X		X		
Monobasic Sodium Phosphate, Anhydrous	X		X		
Dibasic Sodium Phosphate, Anhydrous	X	X	X		
Povidone					
Isopropyl Alcohol	X	X	X		
Lactose Monohydrate					
Sodium Starch Glycolate					
Magnesium Stearate	X		X		
Opadry White Coating					

U.S. EPA label information
Not applicable



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16. Other information

Prepared by:	Beach Products, Inc. Regulatory Affairs
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Revision note:	NA

General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet