



SAFETY DATA SHEET

Potassium Phosphates Injection, USP

SDS DATE: 21-Aug-2019

SECTION 1: IDENTIFICATION

PRODUCT NAME: Potassium Phosphates Injection, USP

SYNONYMS: N/A

NDC Number(s): 46287-024-15

MANUFACTURER: CMP Pharma, Inc.

ADDRESS: PO Box 147

8026 US Hwy. 264A

Farmville, NC 27828

EMERGENCY PHONE: 1-800-227-6637

CHEMTREC PHONE: 1-908-859-2151

OTHER CALLS: 1-252-753-7111

CHEMICAL NAME (for active ingredient): Potassium Phosphate Monobasic and Dibasic

CHEMICAL FAMILY (for active ingredient): Not determined

CHEMICAL FORMULA (for active ingredient): K_2HPO_4 CAS# 7758-11-4

KH_2PO_4 CAS# 7778-77-0

PRODUCT USE: A source of phosphorus, for addition to large volume intravenous fluids, to prevent or correct hypophosphatemia in patients with restricted or no oral intake an additive for preparing specific parenteral fluid formulas when the needs of the patient cannot be met by standard electrolyte or nutrient solutions

SECTION 2: HAZARD(S) IDENTIFICATION

PHYSICAL HAZARDS: Not classified

HEALTH HAZARDS: Not classified

SIGNAL WORD: Not classified

HAZARD STATEMENT: Not classified

HAZARD SYMBOLS: Not classified

PRECAUTIONARY STATEMENTS:

Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Wash hands and face thoroughly after handling. Do not eat, drink, or smoke when using this product. Contaminated work clothing must not be allowed out of the workplace.

If exposure occurs: Get medical advice/attention.

HAZARDS NOT OTHERWISE CLASSIFIED: None classified.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT:	CAS NO.	Amount
Monobasic Potassium Phosphate	7778-77-0	175 mg/mL
Dibasic Potassium Phosphate	7758-11-4	300 mg/mL
Water for Injection	7732-18-5	854 mg/mL



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SECTION 4: FIRST AID MEASURES

- EYE CONTACT:** Flush with copious amounts of water for at least 15 minutes. Hold eyelids away from eyeball to ensure thorough rinsing. Irrigate each eye continuously with normal saline during transport. Seek medical attention immediately.
- SKIN CONTACT:** Wash the affected area with plenty of warm water and soap. If irritation, redness, or rash persists, seek medical attention.
- INGESTION:** Toxicity is low after acute ingestion; gastrointestinal decontamination is generally not necessary. Seek medical advice and monitoring/treatment for allergic reactions.
- INHALATION:** If breathing is difficult, remove to fresh air. Watch for signs of respiratory insufficiency and assist ventilations if needed. Monitor for pulmonary edema and treat if necessary.

MOST IMPORTANT SYMPTOMS/EFFECTS

ACUTE OR DELAYED:

None classified

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS:

This product should only be given to patients by medical professionals educated in the therapy intended for this product. Treat any symptoms and eliminate exposure.

SECTION 5: FIRE-FIGHTING MEASURES

- SUITABLE EXTINGUISHING MEDIA:** Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
- UNSUITABLE EXTINGUISHING MEDIA:** None known.
- UNUSUAL FIRE AND EXPLOSION HAZARDS:** No unusual fire or explosion hazards noted.
- SPECIAL FIRE FIGHTING PROCEDURES:** Evacuate personnel to a safe area. Wear self-contained breathing apparatus and personal protective equipment to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- PERSONAL PRECAUTIONS:** Non-essential personnel should be evacuated from the affected area. Spills should be cleaned up in a manner that minimized exposure to personnel. Personnel involved in the clean up of spills should wear the appropriate respiratory protection, gloves, eye protection, and protective coveralls. Minimize the generation of aerosols. Remove all sources of heat and ignition.
- METHODS/MATERIALS USED FOR CONTAINMENT & CLEANING:** Use a scraper or other device to remove and collect ointment. Minimize the generation of aerosols. Dampen remaining residue with water, then clean spill area thoroughly with soap and water. Collect wash with absorbent material and transfer all waste to a labeled container for disposal. Observe all applicable regulations when disposing of this substance.

SECTION 7: HANDLING AND STORAGE

- HANDLING PRECAUTIONS:** Avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. Wash hands and exposed skin thoroughly with soap and water after use. Remove any contaminated clothing and clean before reuse. Destroy contaminated belts, shoes, and any other items that cannot be decontaminated.



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STORAGE PRECAUTIONS: When not in use, store in a cool, dry, well-ventilated area, in tightly sealed containers that are labeled in accordance with OSHA's Hazard Communication Standard [29CFR 1910.1200]. Keep away from ignition sources including electrostatic charge, heat, sparks, open flame, and strong oxidizers. In case of insufficient ventilation, wear suitable respiratory protection. Keep this drug out of the reach of children.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

EXPOSURE LIMITS/GUIDELINES: No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified. Refer to available public information for specific member state Occupational Exposure Limits.

ENGINEERING CONTROLS: In a manufacturing setting, local exhaust ventilation may be necessary to control air contaminants. The use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces. If user operations generate aerosols, use ventilation to keep exposure to airborne contaminants below the exposure limit.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

EYE PROTECTION: Wear appropriate chemical safety goggles, safety glasses, or face shield as described by OSHA's eye and face protection regulations in 29 CFR 1910.133. Have eyewash stations available where eye contact can occur.

SKIN PROTECTION: Avoid unintended skin contact. Wear gloves impervious to conditions of use. Additional protection may be necessary to prevent skin contact including the use of an apron, face shield, boots, or full body protection. A safety shower should be located in the work area.

RESPIRATORY PROTECTION: If exposure limits are exceeded, approved respiratory protection should be worn. Seek professional assistance for proper selection of respiratory protection.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/ODOR: This product is a clear/colorless liquid solution.

FLASH POINT:	Not established.	% VOLATILE:	Not established.
AUTOIGNITION TEMP:	Not established.	VISCOSITY:	Not established.
BOILING POINT:	Not established.	pH:	6.5 – 7.5.
MELTING POINT:	Not established.	Octanol/H₂O PART. COEFFICIENT:	Not established.
VAPOR PRESSURE (mmHg):	Not established.	POUR POINT:	Not established.
EVAPORATION RATE (H₂O = 1):	Not established.	% SOLUBILITY IN WATER:	Not established.
VAPOR DENSITY (AIR = 1):	Not established.	SPECIFIC GRAVITY (H₂O = 1):	1.3
LOWER FLAMMABILITY LIMIT:	Not established.	UPPER FLAMMABILITY LIMIT:	Not established.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY: No reactivity hazards known.

CHEMICAL STABILITY: Material is stable under normal conditions.

POSSIBILITY OF HAZARDOUS REACTIONS: No dangerous reaction known under conditions of normal use.

CONDITIONS TO AVOID: None known.

INCOMPATIBLE MATERIALS: None Known.



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HAZARDOUS DECOMPOSITION PRODUCTS: Under fire conditions, thermal decomposition may generate irritating and/or toxic fumes or gases (i.e. Oxides of phosphorous).

SECTION 11: TOXICOLOGICAL INFORMATION

INFORMATION ON LIKELY ROUTES OF EXPOSURE:

- INGESTION:** In an occupational setting, ingestion of this product is unlikely. Ingestion may cause irritation.
- INHALATION:** Although unlikely due to product form, inhalation of vapors may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon exposure to fresh air.
- SKIN CONTACT:** Avoid contact with skin. Causes irritation and can be absorbed through the skin in sufficient quantities to cause systemic effects. Other effects may include impaired wound healing, skin atrophy, acne, increased sweating, hypopigmentation, hyperpigmentation, and dermatitis.
- EYE CONTACT:** Avoid contact with eyes. May cause irritation of the eyes.

SIGNS AND SYMPTOMS OF OVEREXPOSURE: None Known.

CHRONIC EFFECTS: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired.

ACUTE TOXICITY: Eye, Skin, and respiratory irritation may occur.

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION:

This product has not been tested for persistence, biodegradability, bioconcentration, soil absorption, or mobility.

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD:

It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with all local, state, and federal regulations. Wear proper protective equipment when handling waste materials.

WASTE DISPOSAL CONTAINERS:

Waste materials must be placed in and shipped in appropriate poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers is done in accordance with all applicable regulations.

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION SHIPPING REGULATIONS:

This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101.

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

TOXIC SUBSTANCE CONTROL ACT (TSCA):

All components of this product are included on the TSCA inventory.

CLEAN WATER ACT (CWA):

There are no ingredients in this mixture listed in the Clean Water Act.



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CLEAN AIR ACT (CAA):

There are no ingredients in this mixture listed under the Clean Air Act.

SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT):

There are no ingredients in this mixture listed under SARA.

STATE REGULATIONS:

This product does not contain chemicals known to the State of California to cause cancer, birth defects, or reproductive harm.

INTERNATIONAL REGULATIONS:

CANADIAN ENVIRONMENTAL PROTECTION ACT:

Listed

CANADIAN WORKPLACE HAZARDOUS MATERIALS INFORMATION SYSTEMS (WHMIS):

Listed

EUROPEAN INVENTORY OF EXISTING CHEMICALS (EINECS):

Listed

EU CLASSIFICATION:

European labeling in accordance with EC directives.

EU RISK (R) AND SAFETY (S) PHRASES (OCCUPATIONAL EXPOSURE):

R38 Irritating to skin
R43 May cause sensitization by skin contact
R61 May cause harm to unborn child
S2 Keep out of the reach of children
S36/27 Wear suitable protective clothing and gloves

SECTION 16: OTHER INFORMATION

NATIONAL FIRE PROTECTION ASSOCIATION (NFPA) RATINGS:

Health: 1 Flammability: 1 Reactivity: 1 Other: 0

CREATION DATE: 20Aug2019 REVISION DATE: N/A

DISCLAIMER: CMP Pharma, Inc. believes that the information contained in this Safety Data Sheet (SDS) is accurate, and while it is provided in good faith, it is without warranty of any kind, express or implied.

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