



AMERICAN REGENT, INC.

**MATERIAL SAFETY DATA SHEET****Section 1: PRODUCT AND COMPANY INFORMATION**

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**PRODUCT NAME:** Potassium Phosphates Injection, USP

**PRODUCT CODE (NDC):** 3 mM/mL Phosphorus; 4.4 mEq/mL Potassium:  
 0517-2305-25, 0517-2315-25, 0517-2350-25

**Section 2: HAZARDS IDENTIFICATION****EMERGENCY OVERVIEW**

Appearance / Odor	Clear, colorless, odorless solution.
<b>WARNING!</b>	
Skin, eye, respiratory and gastrointestinal irritant	Causes irritation of the eyes, skin, gastrointestinal and respiratory tract.
Toxicity to fish/aquatic organisms	Product is not known to be toxic to fish.
<i>Potential Health Effects: See Section 11 for more information</i>	
Likely Routes of Exposure	Eye contact, skin contact, inhalation and ingestion.
Eye	Causes irritation of the eye.
Skin	Causes irritation of the skin.
Inhalation	Causes irritation of the respiratory tract.
Ingestion	Causes irritation of the gastrointestinal tract.
Skin Absorption	Not absorbed through the skin.
Medical Conditions Aggravated by Exposure	Personnel with impaired cardiovascular and kidney function.
Target Organs	Eyes, skin, cardiovascular and central nervous system, kidneys <i>continued on next page</i>

<b>Section 2: HAZARDS IDENTIFICATION (continued)</b>	
<i>Potential Environmental Effects: See Section 12 for more information</i>	This product is not known to be toxic to fish.
This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.	
This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).	

<b>Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS</b>		
Component	CAS Number	Percentage (%) by Weight
Potassium Phosphate (Dibasic)	7758-11-4	23.6 percent
Potassium Phosphate (Monobasic)	7778-77-0	22.4 percent
Water for Injection	7732-18-5	54.0 percent

<b>Section 4: FIRST AID MEASURES</b>	
Eye Contact	Causes eye irritation. Flush for 15 minutes with copious quantities of water. Seek medical attention.
Skin Contact	Causes skin irritation. Remove contaminated clothing. Flush area with copious quantities of water for 15 minutes. Seek medical attention.
Inhalation	Causes irritation of respiratory tract. Remove person to fresh air. Remove contaminated clothing. Seek medical attention.
Ingestion	Causes irritation of the gastrointestinal tract. Flush mouth out with water. Seek medical attention.
Injection	See prescribing information.
Note to Physicians	Adverse reactions to the product may result in abnormal electrocardiogram, arrhythmia, hypotension, confusion and weakness. See prescribing information.

<b>Section 5: FIRE FIGHTING MEASURES</b>	
Suitable Extinguishing Media	Water spray, foam, dry chemical or Carbon Dioxide (CO <sub>2</sub> ). <b>Caution:</b> CO <sub>2</sub> will displace air in confined spaces and may cause an Oxygen deficient atmosphere.
Unsuitable Extinguishing Media	None.
Hazardous Combustion Products	When heated, Potassium Phosphates solution thermally decomposes to form toxic vapors. (i.e. oxides of Phosphorous and Potassium).
<b>Protection for Firefighters:</b> Potassium Phosphates solution thermally decomposes to form toxic vapors. Vapors may be irritating to eyes and skin and toxic to respiratory tract. Firefighters are to wear self-contained breathing apparatus (SCBA) and full turn out gear (Bunker gear). Cool containers with water spray and use caution when approaching.	

<b>Section 6: ACCIDENTAL RELEASE MEASURES</b>	
Personnel Precautions	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
Environmental Precautions	This material is not considered a water pollutant. However, it is recommended to prevent spilled or leaking material from entering waterways. Minimize the use of water to prevent environmental contamination.
Methods of Containment	Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions.
Methods of Clean Up	Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.
Other Information	A spill of this material does not need to be reported to the National Response Center.

<b>Section 7: HANDLING AND STORAGE</b>
<p><u>Handling:</u></p> <p>As a general rule, when handling pharmaceutical products, avoid all contact and inhalation of mists or vapors associated with the product. Avoid contact with skin, eyes and clothing. Do not mix with other drugs.</p> <p>Use in a well ventilated area. Wash thoroughly after handling.</p> <p><u>Storage:</u></p> <p>Store in well ventilated area. Keep containers closed when not in use. Product residue may remain in empty containers. Observe all label precautions until container is cleaned, discarded or destroyed.</p>

<b>Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION</b>			
Exposure Guidelines	OSHA PEL	ACGIH TLV	OTHER
Potassium Phosphate (Dibasic)	Not listed	Not listed	
Potassium Phosphate (Monobasic)	Not listed	Not listed	
Water for Injection	Not listed	Not listed	
Personal Protective Equipment	Description		
Ventilation	Local exhaust or general ventilation is recommended.		
Respiratory Protection	Under normal conditions of product use, respiratory protection is not required. When required, use a NIOSH approved air purifying respirator with P-100 / acid gas cartridges.		
Eye Protection	Wear ANSI approved chemical splash goggles or safety glasses.		
Skin Protection	When administering this product to patients, wear nitrile or latex gloves. Use Tyvek™ SL or equivalent coveralls, PVC booties and nitrile gloves for clean up activities.		

<b>Section 9: PHYSICAL AND CHEMICAL PROPERTIES</b>	
Color	Clear, colorless solution
Odor / Odor Threshold	Odorless
Physical State	Liquid
pH	N/A
Freezing Point	Highest known value is 32 degrees Fahrenheit (Water for Injection)
Boiling Point	Lowest known value is 212 degrees Fahrenheit (Water for Injection)
Flash Point	Not applicable
Evaporation Rate	Not applicable
Flammability	Nonflammable, noncombustible
Upper Flammable Limit	Not applicable
Lower Flammable Limit	Not applicable
Vapor Pressure	Not applicable
Vapor Density	Not applicable
Specific Gravity	Approximately 1.0
Solubility (water)	Freely soluble in water
Partition Coefficient	Not applicable
Auto-ignition Temperature	Not applicable
Percent Volatile	0 percent
Volatile Organic Compounds (%)	0 percent

<b>Section 10: STABILITY AND REACTIVITY</b>	
Stability	Stable.
Conditions to Avoid	Do not mix with other drugs. Avoid heat, light and humidity. Keep away from flames, thermally decomposes to form toxic vapors.
Incompatible Materials	Generally, not reactive.
Hazardous Decomposition Products	Oxides of Phosphorus and Potassium may be released by thermal decomposition.
Possibility of Hazardous Reactions	Hazardous polymerization will not occur.
<b>Section 11: TOXICOLOGY INFORMATION</b>	
<b>Acute Effects</b>	
Oral (LD <sub>LO</sub> )	LD <sub>LO</sub> : 4640 mg/kg oral - rat
Intravenous (LD <sub>50</sub> )	No data available
Intraperitoneal (LD <sub>50</sub> )	No data available
Subcutaneous (LD <sub>50</sub> )	No data available
Dermal (LD <sub>50</sub> )	LD <sub>50</sub> : 4640 mg/kg skin - rabbit
Inhalation	Respiratory irritation is possible.
Eye Irritation	Eye irritation is possible.
Skin Irritation	Skin irritation is possible.
Sensitization	No data available on product's sensitivity.
<b>Chronic Effects</b>	
Organ Systems	Chronic exposure may lead to abnormalities associated with the cardiovascular system and kidneys. May cause kidney stones.
Carcinogenicity	Not considered carcinogenic. No adequate and well controlled studies in humans concerning the carcinogenic effects of Potassium Phosphate have been conducted.
Mutagenicity	Not considered mutagenic. No adequate and well controlled studies in humans concerning the mutagenic effects of Potassium Phosphate have been conducted.

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<b>Section 11: TOXICOLOGY INFORMATION (continued)</b>	
Reproductive Effects	Not considered a reproductive toxin. No adequate and well controlled studies in humans concerning the reproductive effects of Potassium Phosphate have been conducted.
Developmental Effects	Not considered teratogenic. No adequate and well controlled studies in humans concerning the teratogenic effects of Potassium Phosphate have been conducted. Classified as Pregnancy Category C
<b>Section 12: ECOLOGICAL INFORMATION</b>	
Ecotoxicity	No data available
Persistence / Degradability	Short term products of biodegradation are not likely. No data available on the long term degradation of the product.
Bioaccumulation / Accumulation	No applicable bioaccumulation is expected in the environment.
Mobility in Environment	Appreciable volatilization is not expected into the air. Freely mobile in the aquatic environment.
<b>Section 13: DISPOSAL CONDITIONS</b>	
Disposal	Do not mix with other substances. Dispose of in accordance with Federal, state and local regulations. Contact your state or local government environmental and / or sanitation department for guidance on disposal.
<b>Section 14: TRANSPORTATION INFORMATION</b>	
<b>Regulatory Agency</b>	<b>Shipping Description</b>
US DOT (ground)	Not considered a DOT regulated material - Non hazardous for shipment.
Canadian TDG (ground)	See US DOT.
IATA (air)	Not considered a DOT regulated material - Non hazardous for shipment.

<b>Section 15: REGULATORY INFORMATION</b>	
STATE RIGHT TO KNOW	Refer to the applicable state to determine applicability.
California Safe Drinking Water & Toxic Enforcement Act (Prop 65)	This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins under California Proposition 65.
RTECS Number	Potassium Phosphate (Monobasic) - TC6615500
TSCA	8b Inventory - Potassium Phosphates
NFPA Rating	Health - 2, Fire - 0, Reactivity - 0
WHMIS (Canada)	D-2B - Causes other toxic effects

<b>Section 16: OTHER INFORMATION</b>
<p><u>Potassium Phosphates Injection, USP, 3 mM P /mL</u>, is indicated as a source of Phosphorus, for addition to large volume intravenous fluids, to prevent or correct hypophosphatemia in patients with restricted or no oral intake. It is also useful as an additive for preparing specific intravenous fluid formulas when the needs of the patient cannot be met by standard electrolyte or nutrient solutions. The concomitant amount of Potassium (4.4 mEq/mL) must be calculated into the total electrolyte content of such prepared solutions.</p> <p>Refer to Luitpold / American Regent's prescribing information for further information at <a href="http://www.americanregent.com/product_index.asp">http://www.americanregent.com/product_index.asp</a></p> <p>Prepared By: Christopher Seniuk CIH CSP</p>

*The information above is believed to be accurate and represents the best information currently available to American Regent. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall Luitpold, its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if Luitpold has been advised of the possibility of such damages.*