Potassium Phosphates in Sodium Chloride Injection

Safety Data Sheet

According To Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules And Regulations And According To The Hazardous Products Regulation (December 15, 2022).

Date of Issue: 03/17/2025 Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Potassium Phosphates in Sodium Chloride Injection

Synonyms: Phosphorus 15 mmol/100mL and Potassium 22 mEq/100mL
Phosphorus 15 mmol/250mL and Potassium 22 mEq/250mL

1.2 Recommended Use and Restrictions on Use

Use of the Substance/Mixture: Pharmaceuticals

Restrictions on use: No additional information available

1.3. Name, Address, and Telephone of the Responsible Party

Manufacturer

Infomed Fluids SRL
Blvd. Theodor Pallady Nr. 50, Sector 3,
Bucuresti, 032266, Romania (ROU),
(Bucharest, 32266 Romania)

Distributor

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
http://www.fresenius-kabi.com/us/

1.4. Emergency Telephone Number

Emergency Number : VelocityEHS
(800)255-3924 (North America)
+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Not classified.

2.2. Label Elements

GHS-US/CA Labeling

No labeling applicable according to 29 CFR 1910.1200 and the Hazardous Products Regulations (HPR) SOR/2022-272.

2.3 Hazards associated with known or reasonably anticipated uses

If this product is used in unforeseeable chemical processes and not used as intended or reasonable, the hazards listed in Section 2.3 cannot cover all chemistries. Therefore, a Process Hazard Analysis (PHA) or other hazard assessment for additional specific end uses should be performed to ensure that hazards are fully understood, and adequate safety measures are in place. See Section 10 for relevant reactivity and stability information.

2.4. Other Hazards

Exposure may aggravate pre-existing eye, skin, respiratory, kidney and cardiovascular conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Water	Aqua	(CAS-No.) 7732-18-5	96.8 – 98.18	Not classified.

Dipotassium phosphate	Phosphoric acid, dipotassium salt / Potassium phosphate dibasic / Phosphoric acid, potassium salt (1:2) / Dipotassium hydrogen orthophosphate / Dipotassium orthophosphate / Dipotassium hydrogen phosphate / Dibasic potassium phosphate	(CAS-No.) 7758-11-4	0.472 – 1.18	Not classified.
Phosphoric acid, potassium salt (1:1)	Dihydrogen potassium phosphate / Monopotassium phosphate / Phosphoric acid, monopotassium salt / Potassium dihydrogen phosphate / Potassium phosphate, monobasic / Potassium dihydrogenphosphate / Potassium phosphate monobasic / Potassium phosphate / Potassium dihydrogen orthophosphate / Monopotassium orthophosphate / Monopotassium salt of phosphoric acid / Monobasic potassium phosphate	(CAS-No.) 7778-77-0	0.448 – 1.12	Not classified.
Sodium chloride	Sea salt / Sodium chloride (NaCl) / Sodium salt of hydrochloric acid / Salt	(CAS-No.) 7647-14-5	0.9	Not classified.

*Percentages are listed in weight by weight percentage (w/w%).

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.

Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

Ingestion: Rinse mouth. Do NOT induce vomiting. Get medical advice and attention if you feel unwell.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Not expected to present a significant hazard under anticipated conditions of normal use.

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: Prolonged exposure may cause skin irritation.

Eye Contact: May cause slight irritation to eyes.

Ingestion: Ingestion of large quantities may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media suitable for surrounding type of fire.

Unsuitable Extinguishing Media: None.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Not flammable. Use firefighting measures appropriate for the surrounding fire.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Chlorine compounds. Phosphorus oxides.

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray).

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Accidental injection may cause pain and swelling at the injection site. Sharps should be handled appropriately to minimize risk of accidents. If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store at 20 °C to 25 °C (68 °F to 77 °F) [see USP Controlled Room Temperature]. Do not remove solution container from its overwrap until immediately before use. Product should be used within 60 days of removal from overwrap.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

Storage Temperature: Store at 20 °C to 25 °C (68 °F to 77 °F) [see USP Controlled Room Temperature].

7.3. Specific End Use(s)

Pharmaceuticals

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

8.2. Exposure Controls

Appropriate Engineering Controls: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles.

Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	:	Liquid
Color	:	Clear
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	6.0 – 7.0
Evaporation Rate	:	No data available
Melting Point	:	≈ 0 °C (32 °F)
Freezing Point	:	≈ 0 °C (32 °F)
Boiling Point	:	≈ 100 °C (212 °F)
Flash Point	:	No data available
Auto-ignition Temperature	:	No data available
Decomposition Temperature	:	No data available
Flammability (solid, gas)	:	Not applicable
Lower Flammable Limit	:	No data available
Upper Flammable Limit	:	No data available
Vapor Pressure	:	No data available
Relative Vapor Density at 20 °C	:	No data available
Relative Density	:	≈ 1
Specific Gravity	:	No data available
Solubility	:	Water: Soluble
Partition Coefficient: N-Octanol/Water	:	No data available
Viscosity, Kinematic	:	No data available
Particle Aspect Ratio	:	Not applicable
Particle Aggregation State	:	Not applicable
Particle Agglomeration State	:	Not applicable
Particle Specific Surface Area	:	Not applicable
Particle Dustiness	:	Not applicable

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions, Including those Associated with Foreseeable Emergencies:

Hazardous polymerization will not occur.

10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials:

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products:

Thermal decomposition may produce: Chlorine compounds. Phosphorus oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Likely routes of exposure: Dermal. Eye contact. Ingestion.

Acute Toxicity (Oral): Not classified.

Acute Toxicity (Dermal): Not classified.

Acute Toxicity (Inhalation): Not classified.

LD50 and LC50 Data: No additional information available

Skin Corrosion/Irritation: Not classified.

Eye Damage/Irritation: Not classified.

Respiratory or Skin Sensitization: Not classified.

Germ Cell Mutagenicity: Not classified.

Carcinogenicity: Not classified.

Specific Target Organ Toxicity (Repeated Exposure): Not classified.

Reproductive Toxicity: Not classified.

Specific Target Organ Toxicity (Single Exposure): Not classified.

Aspiration Hazard: Not classified.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion of large quantities may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Water (7732-18-5)	
LD50 Oral Rat	> 90 ml/kg (Source: FOOD_JOURN)

Sodium chloride (7647-14-5)	
LD50 Oral Rat	3550 mg/kg (Species: Wistar)
LD50 Dermal Rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation Rat	> 42 mg/l (Exposure time: 1 h Source: ECHA_API)

Dipotassium phosphate (7758-11-4)	
LD50 Oral Rat	> 2000 mg/kg (No death)
LD50 Dermal Rabbit	> 5000 mg/kg (Source: ECHA_API)

Phosphoric acid, potassium salt (1:1) (7778-77-0)	
LD50 Oral Rat	> 2000 mg/kg (No deaths)
LD50 Dermal Rat	> 2000 mg/kg (No deaths)
LC50 Inhalation Rat	> 0.83 mg/l/4h (No deaths)

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

Sodium chloride (7647-14-5)	
LC50 Fish	5560 – 6080 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 Crustacea	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static] Source: EPA)
EC50 Crustacea	340.7 – 469.2 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
NOEC Chronic Fish	252 mg/l (Species: Pimephales promelas)

Phosphoric acid, potassium salt (1:1) (7778-77-0)	
LC50 Fish	> 100 mg/l (Read across)

12.2. Persistence and Degradability

Potassium Phosphates in Sodium Chloride Injection	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Potassium Phosphates in Sodium Chloride Injection	
Bioaccumulative Potential	Not established.

Sodium chloride (7647-14-5)	
BCF Fish	No bioaccumulation.

12.4. Mobility in Soil

No additional information available

12.5. Other Adverse Effects

Other Information: Avoid unnecessary release into the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Treatment Methods: Product contaminated with biological materials should preferably be incinerated.

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Ecology - Waste Materials: Avoid unnecessary release into the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Not regulated for transport

14.2. In Accordance with IMDG

Not regulated for transport

14.3. In Accordance with IATA

Not regulated for transport

14.4. In Accordance with TDG

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Water (7732-18-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Sodium chloride (7647-14-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Dipotassium phosphate (7758-11-4)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Phosphoric acid, potassium salt (1:1) (7778-77-0)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

15.2. US State Regulations

Neither this product nor its chemical components appear on any US state lists, or its chemical components are not required to be disclosed.

15.3. Canadian Regulations

Water (7732-18-5)
Listed on the Canadian DSL (Domestic Substances List)

Sodium chloride (7647-14-5)
Listed on the Canadian DSL (Domestic Substances List)

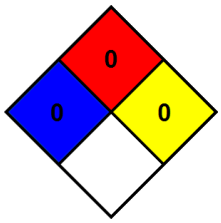
Dipotassium phosphate (7758-11-4)
Listed on the Canadian DSL (Domestic Substances List)

Phosphoric acid, potassium salt (1:1) (7778-77-0)
Listed on the Canadian DSL (Domestic Substances List)

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 03/17/2025

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2022-272.



NFPA Health Hazard : 0 - Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials.

NFPA Fire Hazard : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

NFPA Reactivity Hazard : 0 - Material that in themselves are normally stable, even under fire conditions.

HMIS III Rating

Health : 0 Minimal Hazard - No significant risk to health

Flammability : 0 Minimal Hazard

Physical : 0 Minimal Hazard

Glossary of Data Source Abbreviations

ATSDR: Agency for Toxic Substances and Disease Registry (U.S. Department of Health and Human Services)
AU_WES: Australia WES
CHEMVIEW: ChemView (U.S. Environmental Protection Agency)
EC_RAR: European Commission Renewal Assessment Report
EC_SCOEL: European Commission Scientific Committee on Occupational Exposure Limits
ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals Reports
ECHA_API: European Chemicals Agency API
ECHA_RAC: ECHA Committee for Risk Assessment
EFSA: European Food Safety Authority
EPA: U.S. Environmental Protection Agency
EPA_AEGL: Acute Exposure Guideline Levels (U.S. Environmental Protection Agency)
EPA_FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act Reregistration Eligibility Decision (U.S. Environmental Protection Agency)
EPA_HPV: High Production Volume Chemicals (U.S. Environmental Protection Agency)
EPA_TRED: Risk Assessment for Tolerance Reassessment Eligibility Decision (U.S. Environmental Protection Agency)
EU_CLH: European Union Harmonised Classification and Labelling Proposal
EU_RAR: European Union Risk Assessment Report
FOOD_JOURN: Food Research Journal (1956)
IARC: The International Agency for Research on Cancer
IDLH: National Institute for Occupational Health and Safety Immediately Dangerous to Life or Health Value Profiles
IUCLID: International Uniform Chemical Information Database
JAPAN_GHS: Japan GHS Basis for Classification Data
JP_J-CHECK: Japan J-Check
KR_NIER: South Korea National Institute of Environmental Research Evaluations
NICNAS: Australia National Industrial Chemicals Notification and Assessment Scheme
NIOSH: National Institute for Occupational Health and Safety (U.S. Department of Health and Human Services)
NLM_CIP: National Library of Medicine ChemID plus database
NLM_HSDB: National Library of Medicine Hazardous Substance Data Bank
NLM_PUBMED: National Library of Medicine PubMed database
NTP: National Toxicology Program
NZ_CCID: New Zealand Chemical Classification and Information Database
OECD_EHSP: Environment, Health, and Safety Publication (Organisation for Economic Co-operation and Development)
OECD_SIDS: Screening Information Data Sets (Organisation for Economic Co-operation and Development)
WHO: World Health Organization

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

NA GHS SDS 2024 (Can, US)