



SAFETY DATA SHEET

Revision date 09-Jan-2025

Version 1.03

Page 1 / 9

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Potassium Phosphates Injection, USP (Hospira Inc.)
Product Code(s) PZ03111
Trade Name: Potassium Phosphates Injection, USP
Chemical Family: Not determined

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product used as electrolyte replacement

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

2.2. Label elements

Signal word Not Classified

Hazard statements Not classified in accordance with international standards for workplace safety.

2.3. Other hazards

Other hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

SAFETY DATA SHEET

Product Name Potassium Phosphates Injection, USP (Hospira Inc.)
Revision date 09-Jan-2025

Page 2 / 9
Version 1.03

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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 for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

Not applicable

3.2 Mixtures

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available
Dibasic Potassium Phosphate (CAS #: 7758-11-4)	23.6		231-834-5	Not classified as hazardous	Not Listed	No data available	No data available
Potassium phosphate (CAS #: 7778-77-0)	22.4	-	231-913-4	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Dibasic Potassium Phosphate 7758-11-4	>2000	5000	No data available	No data available	No data available
Potassium phosphate 7778-77-0	3200	No data available	0.83	No data available	No data available

Additional information

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

SAFETY DATA SHEET

Product Name Potassium Phosphates Injection, USP (Hospira Inc.)
Revision date 09-Jan-2025

Page 3 / 9
Version 1.03

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water. If skin irritation persists, call a physician.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	None.
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Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media	Dry chemical, CO2, alcohol-resistant foam or water spray.
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5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Fine particles (such as mists) may fuel fires/explosions.
Hazardous combustion products	Formation of toxic gases is possible during heating or fire. May include oxides of phosphorous

5.3. Advice for firefighters

Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
For emergency responders	Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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6.3. Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

SAFETY DATA SHEET

Product Name Potassium Phosphates Injection, USP (Hospira Inc.)
Revision date 09-Jan-2025

Page 4 / 9
Version 1.03

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical product used as. electrolyte replacement.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

Refer to available public information for specific member state Occupational Exposure Limits.

Dibasic Potassium Phosphate

Russia

MAC: 10 mg/m³

Potassium phosphate

Russia

MAC: 10 mg/m³

8.2. Exposure controls

Engineering controls Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.

Environmental exposure controls No information available.

Personal protective equipment Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Eye/face protection Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

SAFETY DATA SHEET

Product Name Potassium Phosphates Injection, USP (Hospira Inc.)
Revision date 09-Jan-2025

Page 5 / 9
Version 1.03

Skin and body protection	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).
Respiratory protection	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Color	Colourless
Odor	No information available.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture
Property	Values
pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	Soluble
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

Oxidizing properties	None
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SAFETY DATA SHEET

Product Name Potassium Phosphates Injection, USP (Hospira Inc.)
Revision date 09-Jan-2025

Page 6 / 9
Version 1.03

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as mists) may fuel fires/explosions.

10.5. Incompatible materials

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

10.6. Hazardous decomposition products

Hazardous decomposition products Thermal decomposition products include. Oxides of phosphorus.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information: The information included in this section describes the potential hazards of the active ingredient(s).

Known Clinical Effects: Adverse effects associated with therapeutic use include nausea, vomiting, diarrhea, abdominal pain.

Acute toxicity Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Respiratory or skin sensitization Based on available data, the classification criteria are not met.

STOT - single exposure Based on available data, the classification criteria are not met.

STOT - repeated exposure Based on available data, the classification criteria are not met.

Reproductive toxicity Based on available data, the classification criteria are not met.

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Carcinogenicity Based on available data, the classification criteria are not met.

Aspiration hazard Based on available data, the classification criteria are not met.

Acute Toxicity: (Species, Route, End Point, Dose)

Dibasic Potassium Phosphate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 0.83 mg/L

Rabbit Dermal LD50 > 5000 mg/kg

Potassium phosphate

Rat Oral LD50 3200 mg/kg

Rabbit Dermal LC50 > 4640 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
Dibasic Potassium Phosphate	> 2000 mg/kg	> 5000 mg/kg (Rabbit)	-

SAFETY DATA SHEET

Product Name Potassium Phosphates Injection, USP (Hospira Inc.)
Revision date 09-Jan-2025

Page 7 / 9
Version 1.03

Potassium phosphate	= 3200 mg/kg (Rat)	-	> 0.83 mg/L (Rat) 4 h
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Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Potassium phosphate

Reproductive & Fertility Rat No route specified 282 mg/kg/day NOAEL No evidence of impaired fertility or harm to the fetus
Reproductive & Fertility Mouse No route specified 320 mg/kg/day NOAEL No evidence of impaired fertility or harm to the fetus

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Potassium phosphate

Bacterial Mutagenicity (Ames) *Salmonella* Negative

Carcinogenicity None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

SAFETY DATA SHEET

Product Name Potassium Phosphates Injection, USP (Hospira Inc.)
Revision date 09-Jan-2025

Page 8 / 9
Version 1.03

Chemical name	PBT and vPvB assessment
Dibasic Potassium Phosphate	PBT assessment does not apply
Potassium phosphate	The substance is not PBT / vPvB PBT assessment does not apply

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

UN number: Not applicable
UN proper shipping name: Not applicable
Transport hazard class(es): Not applicable
Packing group: Not applicable
Environmental Hazard(s): Not applicable

Special precautions for user: Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-791-2
AICS	Present

Dibasic Potassium Phosphate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-834-5

SAFETY DATA SHEET

Product Name Potassium Phosphates Injection, USP (Hospira Inc.)
Revision date 09-Jan-2025

Page 9 / 9
Version 1.03

AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6
Potassium phosphate	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-913-4
AICS	Present

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Data Sources:	Publicly available toxicity information.
Reason for revision	Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Revision date	09-Jan-2025
Prepared By	Pfizer Global Environment, Health, and Safety

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