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

#### 1.1. Product identifier

Product Name Sodium Phosphates Injection (Hospira, Inc.)

Product Code(s) PZ03204

Trade Name: Sodium 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 this substance ( see Section 8 ).

Note: This document has been prepared in accordance with standards for workplace safety, which

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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

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Chemical name	Weight-%	REACH	EC No	Classification	Specific	M-Factor	M-Factor
		Registration		according to	concentration		(long-term)
		Number		Regulation	limit (SCL)		, , ,
				(EC) No.	(552)		
				1272/2008			
				[CLP]			
Water	*	-	231-791-2	Not classified	Not Listed	No data	No data
(CAS #: 7732-18-5)				as hazardous		available	available
Sodium phosphate,	*		231-449-2	Not classified	Not Listed	No data	No data
monobasic				as hazardous		available	available
(CAS #: 7558-80-7)							
Sodium phosphate,	*		231-448-7	Not classified	Not Listed	No data	No data
dibasic				as hazardous		available	available
(CAS #: 7558-79-4)							

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

**Acute Toxicity Estimate** 

Chemical name	Oral LD50	Dermal LD50		Inhalation LC50 - 4 hour - vapor - mg/L	
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Sodium phosphate, monobasic 7558-80-7	8290	7940	0.83	No data available	No data available
Sodium phosphate, dibasic 7558-79-4	17000	No data available	No data available	No data available	No data available

# **Additional information**

\* Proprietary

Non-hazardous ingredients provided for completeness. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

# Section 4: FIRST AID MEASURES

# 4.1. Description of first aid measures

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**Inhalation** Move to fresh air. If discomfort persists, get medical attention.

Eye contact Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical

attention.

**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

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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.

### 4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

# Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

Suitable Extinguishing Media As for primary cause of fire.

### 5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

Not applicable.

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.

### 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.

# 6.3. Methods and material for containment and cleaning up

**Methods for containment** Keep away from incompatible materials.

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.

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

#### 6.4. Reference to other sections

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**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.

### Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### **Exposure Limits**

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

Sodium phosphate, monobasic

Russia MAC: 10 mg/m³

Sodium phosphate, dibasic
Russia MAC: 10 mg/m³

MAC: 10 mg/m³

**Pfizer Occupational Exposure Band** 

(OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Sodium phosphate, dibasic

Pfizer Occupational Exposure OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³) Band (OEB):

Sodium phosphate, monobasic

Pfizer Occupational Exposure OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)
Band (OEB):

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** 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. Refer to applicable national standards and regulations in the

selection and use of personal protective equipment (PPE).

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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

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accordance with EN374, ASTM F1001 or international equivalent.).

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 formulaMixtureMolecular weightMixture

Property Values 5.0-6.0

Melting point / freezing point No data available

Boiling point / boiling range

Flash point

Evaporation rate

Flammability (solid, gas)

Flammability Limit in Air

No information available
No data available
No data available

Upper flammability limit: No data available

Lower flammability limit: No data available

Vapor pressureNo data availableVapor densityNo data availableRelative densityNo data available

Water solubility Soluble

Solubility(ies)No data availablePartition coefficientNo data availableAutoignition temperatureNo data availableDecomposition temperatureNo data availableKinematic viscosityNo data availableDynamic viscosityNo data available

Particle characteristics

Particle Size No information available Particle Size Distribution No information available Explosive properties No information available

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#### 9.2. Other information

No information available

### 9.2.1. Information with regard to physical hazard classes

Oxidizing properties None

#### 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 None known.

10.5. Incompatible materials

Incompatible materials None known.

# 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:** This product is composed of non-hazardous ingredients.

Known Clinical 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** Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation
Skin corrosion/irritation
Respiratory or skin sensitization
STOT - single exposure
STOT - repeated exposure
Reproductive toxicity
Based on available data, the classification criteria are not met.
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**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)

Acute Toxicity: (Species, Route, End Point, Dose)						
Chemical name	Oral LD50	Dermal LD50	Inhalation LC50			
Water	> 90 mL/kg (Rat)	-	-			
Sodium phosphate, monobasic	= 8290 mg/kg (Rat)	> 7940 mg/kg (Rabbit)	> 0.83 mg/L (Rat)4 h			
Sodium phosphate, dibasic	= 17 g/kg(Rat)	-	-			

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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

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Other adverse effects No information available.

# Section 12: ECOLOGICAL INFORMATION

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**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

No information available. Persistence and degradability

12.3. Bioaccumulative potential

No information available. Bioaccumulation

12.4. Mobility in soil

No information available. Mobility in soil

# 12.5. Results of PBT and vPvB assessment

### PBT and vPvB assessment

Chemical name	PBT and vPvB assessment	
Sodium phosphate, monobasic	PBT assessment does not apply	
Sodium phosphate, dibasic	PBT assessment does not apply	

### 12.6. Endocrine disrupting properties

No information available. **Endocrine disrupting properties** 

12.7. Other adverse effects

No information available.

# Section 13: DISPOSAL CONSIDERATIONS

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#### 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:
UN proper shipping name:
Not applicable
Not applicable
Not applicable
Not applicable
Not applicable
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

Sodium phosphate, monobasic

CERCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed
TSCA Present
EINECS 231-449-2
AICS Present

Sodium phosphate, dibasic

CERCLA/SARA Section 313 de minimus % Not Listed **Hazardous Substances RQs** 5000 lb **California Proposition 65** Not Listed **TSCA** Present 231-448-7 **EINECS AICS** Present Schedule 5 Standard for Uniform Scheduling of Medicines and Poisons (SUSMP) Schedule 6

### **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

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#### 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. Updated Section 8 - Exposure Controls / Personal Protection.

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Prepared By Pfizer Global Environment, Health, and Safety

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