



# SAFETY DATA SHEET

Revision date 09-Mar-2023

Version 2

Page 1 / 12

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

### 1.1. Product identifier

**Product Name** Dextrose Injection, USP (Hospira, Inc.)  
**Product Code(s)** PZ03049  
**Synonyms** 50% Dextrose Injection, USP Concentrated Dextrose for Intravenous Administration;  
CONCENTRATED DEXTROSE FOR  
INTRAVENOUS ADMINISTRATION TO INFANTS  
**Trade Name:** Not applicable  
**Chemical Family:** Mixture

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

**Recommended Use** Pharmaceutical product used for 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.

**Supplemental Hazard** Compound, not fully tested, additional hazards may exist.

# SAFETY DATA SHEET

Product Name Dextrose Injection, USP (Hospira, Inc.)  
Revision date 09-Mar-2023

Page 2 / 12  
Version 2

## 2.3. Other hazards

### Other hazards

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

### 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

#### Hazardous

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)
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5	Skin Corr.1A (H314)	Eye Irrit. 2 :: 0.5%≤C<2% Skin Corr. 1A :: C≥5% Skin Corr. 1B :: 2%≤C<5% Skin Irrit. 2 :: 0.5%≤C<2%	No data available	No data available
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7	Acute Tox. 3 (H331) Skin Corr. 1A (H314) Press. Gas	Eye Irrit. 2 :: 10%≤C<25% Skin Corr. 1B :: C≥25% Skin Irrit. 2 :: 10%≤C<25% STOT SE 3 :: C≥10%	No data available	No data available

#### 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
Dextrose, monohydrate (CAS #: 5996-10-1)	25-50		Not Listed	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

# SAFETY DATA SHEET

Product Name Dextrose Injection, USP (Hospira, Inc.)  
Revision date 09-Mar-2023

Page 3 / 12  
Version 2

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
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

## Additional information

+ Substance with a Union workplace exposure limit

\* Proprietary

\*\* to adjust pH

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

#### Inhalation

Not an expected route of exposure.

#### Eye contact

If irritation occurs or persists, get medical attention. Flush eyes with water as a precaution.

#### Skin contact

If irritation occurs, wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance.

#### 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

No data available

### 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

Dry chemical, CO<sub>2</sub>, alcohol-resistant foam or water spray.

### 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 carbon sodium

# SAFETY DATA SHEET

Product Name Dextrose Injection, USP (Hospira, Inc.)  
Revision date 09-Mar-2023

Page 4 / 12  
Version 2

## 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** 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.  
**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** No special handling requirements for normal use of this material.  
**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 drug 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.

<b>Sodium hydroxide</b>	
ACGIH OEL (Ceiling)	2 mg/m <sup>3</sup>
ACGIH TLV	Ceiling: 2 mg/m <sup>3</sup>
Austria	2 mg/m <sup>3</sup>
	STEL 4 mg/m <sup>3</sup>
Bulgaria	2.0 mg/m <sup>3</sup>

# SAFETY DATA SHEET

Product Name Dextrose Injection, USP (Hospira, Inc.)  
Revision date 09-Mar-2023

Page 5 / 12  
Version 2

---

Czech Republic	1 mg/m <sup>3</sup> Ceiling: 2 mg/m <sup>3</sup>
Denmark	Ceiling: 2 mg/m <sup>3</sup>
Estonia	1 mg/m <sup>3</sup> STEL: 2 mg/m <sup>3</sup>
Finland	Ceiling: 2 mg/m <sup>3</sup>
France	2 mg/m <sup>3</sup>
Hungary	1 mg/m <sup>3</sup> STEL: 2 mg/m <sup>3</sup>
Ireland	STEL: 2 mg/m <sup>3</sup>
Ceiling Limit Value	2 mg/m <sup>3</sup>
Latvia	0.5 mg/m <sup>3</sup>
Poland	STEL: 1 mg/m <sup>3</sup> 0.5 mg/m <sup>3</sup>
Romania	1 mg/m <sup>3</sup> STEL: 3 mg/m <sup>3</sup>
Slovakia	2 mg/m <sup>3</sup>
Spain	STEL: 2 mg/m <sup>3</sup>
Switzerland	2 mg/m <sup>3</sup> STEL: 2 mg/m <sup>3</sup>
OSHA PEL	2 mg/m <sup>3</sup>
United Kingdom	(vacated) Ceiling: 2 mg/m <sup>3</sup> STEL: 2 mg/m <sup>3</sup>
<b>+ Hydrochloric Acid</b>	
ACGIH OEL (Ceiling)	2 ppm
ACGIH TLV	Ceiling: 2 ppm
Austria	5 ppm 8 mg/m <sup>3</sup> STEL 10 ppm STEL 15 mg/m <sup>3</sup>
Bulgaria	STEL: 10 ppm STEL: 15.0 mg/m <sup>3</sup> 5 ppm 8.0 mg/m <sup>3</sup>
Czech Republic	8 mg/m <sup>3</sup> Ceiling: 15 mg/m <sup>3</sup>
Estonia	5 ppm 8 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
European Union	TWA: 5 ppm TWA: 8 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Finland	STEL: 5 ppm STEL: 7.6 mg/m <sup>3</sup>
Germany	2 ppm 3.0 mg/m <sup>3</sup> Ceiling / Peak: 4 ppm Ceiling / Peak: 6 mg/m <sup>3</sup>
Germany	2 ppm 3 mg/m <sup>3</sup>
Hungary	8 mg/m <sup>3</sup> STEL: 16 mg/m <sup>3</sup>
Ireland	8 mg/m <sup>3</sup> 5 ppm STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Italy	5 ppm 8 mg/m <sup>3</sup>

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# SAFETY DATA SHEET

Product Name Dextrose Injection, USP (Hospira, Inc.)  
Revision date 09-Mar-2023

Page 6 / 12  
Version 2

Ceiling Limit Value	STEL: 10 ppm STEL: 15 mg/m <sup>3</sup> 2 ppm 3.0 mg/m <sup>3</sup>
Latvia	5 ppm 8 mg/m <sup>3</sup>
Netherlands	STEL: 10 ppm STEL: 15 mg/m <sup>3</sup> 8 mg/m <sup>3</sup>
Poland	STEL: 15 mg/m <sup>3</sup> STEL: 10 mg/m <sup>3</sup> 5 mg/m <sup>3</sup>
Romania	5 ppm 8 mg/m <sup>3</sup>
Russia	STEL: 10 ppm STEL: 15 mg/m <sup>3</sup> MAC: 5 mg/m <sup>3</sup>
Slovakia	5 ppm 8.0 mg/m <sup>3</sup>
Spain	5 ppm 7.6 mg/m <sup>3</sup>
Switzerland	STEL: 10 ppm STEL: 15 mg/m <sup>3</sup> 2 ppm 3 mg/m <sup>3</sup>
U.S. - OSHA - Final PELs - Ceiling Limits	STEL: 4 ppm STEL: 6 mg/m <sup>3</sup> 5 ppm 7 mg/m <sup>3</sup>
OSHA PEL	(vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m <sup>3</sup> Ceiling: 5 ppm Ceiling: 7 mg/m <sup>3</sup>
United Kingdom	TWA: 1 ppm TWA: 2 mg/m <sup>3</sup> STEL: 5 ppm STEL: 8 mg/m <sup>3</sup>

## **8.2. Exposure controls**

<b>Engineering controls</b>	Engineering controls should be used as the primary means to control exposures.
<b>Environmental exposure controls</b>	No information available.
<b>Personal protective equipment</b>	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).
<b>Eye/face protection</b>	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.).
<b>Hand protection</b>	Not required for the normal use of this product.
<b>Skin and body protection</b>	Not required for the normal use of this product.
<b>Respiratory protection</b>	None required under normal conditions of use.

# SAFETY DATA SHEET

Product Name Dextrose Injection, USP (Hospira, Inc.)  
Revision date 09-Mar-2023

Page 7 / 12  
Version 2

**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	Colorless
Odor	None.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture

#### Property

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	No data available
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

#### Values

### 9.2. Other information

No information available

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

No information available

#### 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.

#### Explosion data

Sensitivity to Mechanical Impact No data available.

# SAFETY DATA SHEET

Product Name Dextrose Injection, USP (Hospira, Inc.)  
Revision date 09-Mar-2023

Page 8 / 12  
Version 2

**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.

### 10.5. Incompatible materials

**Incompatible materials** None.

### 10.6. Hazardous decomposition products

**Hazardous decomposition products** No data available.

## **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 individual ingredients

**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)

#### Sodium hydroxide

Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
Sodium hydroxide	= 325 mg/kg ( Rat )	= 1350 mg/kg ( Rabbit )	-
+ Hydrochloric Acid	238 - 277 mg/kg ( Rat )	> 5010 mg/kg ( Rabbit )	= 1.68 mg/L ( Rat ) 1 h

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

### Irritation / Sensitization: (Study Type, Species, Severity)

#### Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

#### + Hydrochloric Acid

Skin irritation Severe

Eye irritation Severe

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

#### + Hydrochloric Acid

Bacterial Mutagenicity (Ames) *Salmonella* Negative

*In Vivo* Micronucleus Rat Negative



# SAFETY DATA SHEET

Product Name Dextrose Injection, USP (Hospira, Inc.)  
Revision date 09-Mar-2023

Page 9 / 12  
Version 2

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

**+ Hydrochloric Acid**  
IARC Group 3 (Not Classifiable)

## 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:** Releases to the environment should be avoided. No acute toxicity to aquatic organisms is expected Based on available data, the classification criteria are not met.

### 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**

Chemical name	PBT and vPvB assessment
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does not apply
+ Hydrochloric Acid	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**

# SAFETY DATA SHEET

Product Name Dextrose Injection, USP (Hospira, Inc.)  
Revision date 09-Mar-2023

Page 10 / 12  
Version 2

## 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

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

Dextrose, monohydrate

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed

Sodium hydroxide

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>Hazardous Substances RQs</b>	1000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	215-185-5
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5 Schedule 6

+ Hydrochloric Acid

<b>CERCLA/SARA Section 313 de minimus %</b>	1.0 %
<b>Hazardous Substances RQs</b>	5000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-595-7
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5 Schedule 6

# SAFETY DATA SHEET

Product Name Dextrose Injection, USP (Hospira, Inc.)  
Revision date 09-Mar-2023

Page 11 / 12  
Version 2

## 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 contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Sodium hydroxide - 1310-73-2	Use restricted. See item 75.	
+ Hydrochloric Acid - 7647-01-0	Use restricted. See item 75.	

### Persistent Organic Pollutants

Not applicable

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

Not applicable

### Named dangerous substances per Seveso Directive (2012/18/EU)

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
+ Hydrochloric Acid - 7647-01-0	25	250

### EU - Biocides

Chemical name	EU - Biocides
+ Hydrochloric Acid - 7647-01-0	Product-type 2: Disinfectants and algacides not intended for direct application to humans or animals

### 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

#### Full text of H-Statements referred to under section 3

Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage. Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation.

**Data Sources:** Publicly available toxicity information.

**Reason for revision** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

**Revision date** 09-Mar-2023

# SAFETY DATA SHEET

Product Name Dextrose Injection, USP (Hospira, Inc.)  
Revision date 09-Mar-2023

Page 12 / 12  
Version 2

---

**Prepared By** Pfizer Global Environment, Health, and Safety

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