



# SAFETY DATA SHEET

Revision date 26-Feb-2023

Version 2

Page 1 / 13

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

### 1.1. Product identifier

**Product Name** Cytarabine Injection, solution (Hospira, inc.)  
**Product Code(s)** PZ03474  
**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 as Antineoplastic

### 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

Hospira UK Limited  
Horizon  
Honey Lane  
Hurley  
Maidenhead, SL6 6RJ  
United Kingdom

**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: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

**Germ cell mutagenicity** Category 1B - (H340)  
**Reproductive toxicity** Category 1B - (H360D)

### 2.2. Label elements

**Signal word** Danger

**Hazard statements** H340 - May cause genetic defects  
H360D - May damage the unborn child

**Precautionary Statements** P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P280 - Wear protective gloves and protective clothing  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with all local and national regulations

# SAFETY DATA SHEET

Product Name Cytarabine Injection, solution (Hospira, inc.)  
Revision date 26-Feb-2023

Page 2 / 13  
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)
Cytarabine (CAS #: 147-94-4)	2-10		205-705-9	Muta. 1B (H340) Repr. 1B (H360D)	Not Listed	No data available	No data available
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified as hazardous	Not Listed	No data available	No data available
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	EC No	Classification according to	Specific concentration	M-Factor	M-Factor (long-term)
---------------	----------	--------------------	-------	-----------------------------	------------------------	----------	----------------------

# SAFETY DATA SHEET

Product Name Cytarabine Injection, solution (Hospira, inc.)  
Revision date 26-Feb-2023

Page 3 / 13  
Version 2

		Number		Regulation (EC) No. 1272/2008 [CLP]	limit (SCL)		
Water (CAS #: 7732-18-5)	*	-	231-791-2	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

No information available

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
Cytarabine 147-94-4	>3000	No data available	No data available	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3000	10000	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

\* Proprietary

\*\* to adjust pH

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. Non-hazardous ingredients provided for completeness.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	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.

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

# SAFETY DATA SHEET

Product Name Cytarabine Injection, solution (Hospira, inc.)  
Revision date 26-Feb-2023

Page 4 / 13  
Version 2

**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** Fine particles (such as dust and mists) may fuel fires/explosions.

**Hazardous combustion products** Formation of toxic gases is possible during heating or fire.

### **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**

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.

# SAFETY DATA SHEET

Product Name Cytarabine Injection, solution (Hospira, inc.)  
Revision date 26-Feb-2023

Page 5 / 13  
Version 2

## 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.

#### Cytarabine

Pfizer OEL TWA-8 Hr: 2 µg/m<sup>3</sup>

#### SODIUM CHLORIDE

Latvia 5 mg/m<sup>3</sup>  
Russia MAC: 5 mg/m<sup>3</sup>

#### Sodium hydroxide

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>  
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>  
(vacated) Ceiling: 2 mg/m<sup>3</sup>  
STEL: 2 mg/m<sup>3</sup>  
United Kingdom

#### + Hydrochloric Acid

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>

# SAFETY DATA SHEET

Product Name Cytarabine Injection, solution (Hospira, inc.)  
Revision date 26-Feb-2023

Page 6 / 13  
Version 2

---

European Union	STEL: 10 ppm STEL: 15 mg/m <sup>3</sup> 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>
Ireland	STEL: 16 mg/m <sup>3</sup> 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> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Ceiling Limit Value	2 ppm 3.0 mg/m <sup>3</sup>
Latvia	5 ppm 8 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Netherlands	8 mg/m <sup>3</sup> STEL: 15 mg/m <sup>3</sup>
Poland	STEL: 10 mg/m <sup>3</sup> 5 mg/m <sup>3</sup>
Romania	5 ppm 8 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Russia	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> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Switzerland	2 ppm 3 mg/m <sup>3</sup> STEL: 4 ppm STEL: 6 mg/m <sup>3</sup>
U.S. - OSHA - Final PELs - Ceiling Limits	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>

# SAFETY DATA SHEET

Product Name Cytarabine Injection, solution (Hospira, inc.)  
Revision date 26-Feb-2023

Page 7 / 13  
Version 2

## 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.

## 8.2. Exposure controls

### Engineering controls

General room ventilation is adequate unless the process generates dust, mist or fumes. Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section.

### 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 disposable gloves (e.g. Nitrile, etc.) (double 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.).

### 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 full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, 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	Solution
Color	Colorless
Odor	No information available.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture
<b>Property</b>	<b>Values</b>
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	

# SAFETY DATA SHEET

Product Name Cytarabine Injection, solution (Hospira, inc.)  
Revision date 26-Feb-2023

Page 8 / 13  
Version 2

<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Relative density</b>	No data available
<b>Water solubility</b>	No data available
<b>Solubility(ies)</b>	No data available
<b>Partition coefficient</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Kinematic viscosity</b>	No data available
<b>Dynamic viscosity</b>	No data available
<b>Particle characteristics</b>	
<b>Particle Size</b>	No information available
<b>Particle Size Distribution</b>	No information available
<b>Explosive properties</b>	No information available

## 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 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 dust and 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** 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

**Short term** May cause eye and skin irritation (based on components)

**Long Term:** Animal studies have shown a potential to cause adverse effects on the fetus.



# SAFETY DATA SHEET

Product Name Cytarabine Injection, solution (Hospira, inc.)  
Revision date 26-Feb-2023

Page 9 / 13  
Version 2

**Known Clinical Effects:** Bone marrow suppression is the most serious adverse effect seen during clinical use. Adverse effects seen in clinical use include gastrointestinal discomfort, dizziness, and headache.

**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** May damage the unborn child.  
**Germ cell mutagenicity** May cause genetic defects.  
**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)**

**Cytarabine**

Rat Oral LD 50 > 3000 mg/kg  
 Rat Para-periosteal LD 50 > 5000 mg/kg  
 Mouse Oral LD 50 3150 mg/kg  
 Mouse Intravenous LD 50 > 7000 mg/kg

**SODIUM CHLORIDE**

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m<sup>3</sup>  
 Rat Oral LD 50 3 g/kg  
 Mouse Oral LD 50 4 g/kg  
 Rabbit Dermal LD 50 > 10 g/kg

**Sodium hydroxide**

Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
Cytarabine	> 5 g/kg ( Rat )	-	-
SODIUM CHLORIDE	= 3 g/kg ( Rat )	> 10000 mg/kg ( Rabbit )	> 42 mg/L ( Rat ) 1 h
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)**

**Cytarabine**

Eye Irritation Rabbit Minimal  
 Skin Irritation Rabbit Mild

**SODIUM CHLORIDE**

Skin irritation Rabbit Mild  
 Eye irritation Rabbit Mild

**Sodium hydroxide**

Eye Irritation Rabbit Severe  
 Skin Irritation Rabbit Severe

**+ Hydrochloric Acid**

Skin irritation Severe  
 Eye irritation Severe

**Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

**Cytarabine**

# SAFETY DATA SHEET

Product Name Cytarabine Injection, solution (Hospira, inc.)  
Revision date 26-Feb-2023

Page 10 / 13  
Version 2

Embryo / Fetal Development Mouse  $\geq$  2 mg/kg/day LOAEL Teratogenic  
Embryo / Fetal Development Rat 20 mg/kg LOAEL Teratogenic  
Embryo / Fetal Development Rat 50 mg/kg LOAEL Developmental toxicity  
Embryo / Fetal Development Mouse 8 mg/kg/day LOAEL Fetotoxicity

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

### Cytarabine

*In Vivo* Chromosome Aberration Rodent Bone Marrow Positive  
*In Vivo* Sister Chromatid Exchange Rodent Bone Marrow Positive  
*In Vivo* Micronucleus Mouse Positive  
*In Vitro* Chromosome Aberration Human Lymphocytes Positive  
*In Vitro* Human Lymphocytes Positive

### + Hydrochloric Acid

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
*In Vivo* Micronucleus Rat Negative

## Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

### Cytarabine

72 Week(s) Rat Oral 25 mg/kg/day NOAEL Not carcinogenic

### Carcinogenicity

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

### + 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:** Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

### 12.1. Toxicity

### 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

# SAFETY DATA SHEET

Product Name Cytarabine Injection, solution (Hospira, inc.)  
Revision date 26-Feb-2023

Page 11 / 13  
Version 2

**PBT and vPvB assessment** No information available.

Chemical name	PBT and vPvB assessment
SODIUM CHLORIDE	The substance is not PBT / vPvB PBT assessment does not apply
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

### 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

Cytarabine

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
---	------------

# SAFETY DATA SHEET

Product Name Cytarabine Injection, solution (Hospira, inc.)  
 Revision date 26-Feb-2023

Page 12 / 13  
 Version 2

<b>California Proposition 65</b>	developmental toxicity 1/1/1989
<b>EINECS</b>	205-705-9
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 4
<b>SODIUM CHLORIDE</b>	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-598-3
<b>AICS</b>	Present
<b>Sodium hydroxide</b>	
<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
<b>+ Hydrochloric Acid</b>	
<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

Chemical name	French RG number	Title
SODIUM CHLORIDE 7647-14-5	RG 78	-

### 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)

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

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

Chemical name	Plant protection products directive (91/414/EEC)
SODIUM CHLORIDE - 7647-14-5	Plant protection agent

Chemical name	EU - Biocides

# SAFETY DATA SHEET

Product Name Cytarabine Injection, solution (Hospira, inc.)  
Revision date 26-Feb-2023

Page 13 / 13  
Version 2

+ 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

Reproductive toxicity-Cat.1B; H360D - May damage the unborn child Germ cell mutagenicity-Cat.1B; H340 - May cause genetic defects Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled

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

**Reason for revision** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information.

**Revision date** 26-Feb-2023

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

**Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.**