



# SAFETY DATA SHEET

Revision date 16-Jun-2025

Version 6

Page 1 / 12

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

### 1.1. Product identifier

**Product Name** Fludarabine Phosphate Injection  
**Product Code(s)** PZ01778  
**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

Pfizer Inc  
66 Hudson Boulevard East  
New York, New York 10001  
1-800-879-3477

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

**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 - (H360FD)

### OSHA Classification

**Hazards not otherwise classified (HNOC)**

Not applicable

**Hazards classified under paragraph (d)(1)(ii) of 1910.1200**

Not applicable

### 2.2. Label elements



# SAFETY DATA SHEET

Product Name Fludarabine Phosphate Injection  
Revision date 16-Jun-2025

Page 2 / 12  
Version 6

**Signal word** Danger  
**Hazard statements** H340 - May cause genetic defects  
H360FD - May damage fertility. May damage the unborn child

**Precautionary Statements - EU (§28, 1272/2008)** 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 advice/attention  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

## 2.3. Other hazards

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

**PBT & vPvB** The product does not contain any substance(s) classified as PBT or vPvB.

**Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors.

**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 (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Fludarabine phosphate (CAS #: 75607-67-9)	5		Not Listed	Muta. 1B (H340) Repr. 1B (H360FD)	Not classified	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	##	-	215-185-5 (011-002-00-6)	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

NonHazardous

Chemical name	Weight-%	REACH	EC No (EU	Classification	Specific	M-Factor	M-Factor
---------------	----------	-------	-----------	----------------	----------	----------	----------

# SAFETY DATA SHEET

Product Name Fludarabine Phosphate Injection  
Revision date 16-Jun-2025

Page 3 / 12  
Version 6

		registration number	Index No)	according to Regulation (EC) No. 1272/2008 [CLP]	concentration limit (SCL)		(long-term)
Mannitol (CAS #: 69-65-8)	*	-	200-711-8	Not classified	Not classified	No data available	No data available
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	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 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Mannitol 69-65-8	13500	No data available	No data available	No data available	No data available
Fludarabine phosphate 75607-67-9	>2000	No data available	No data available	No data available	No data available
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

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59).

## 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** For information on potential signs and symptoms of exposure, See Section 2 - Hazards

# SAFETY DATA SHEET

Product Name Fludarabine Phosphate Injection  
Revision date 16-Jun-2025

Page 4 / 12  
Version 6

**effects** 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** Dry chemical, CO2, 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.

#### **Explosion data**

**Sensitivity to mechanical impact** No information available.

**Sensitivity to static discharge** No information available.

### **5.3. Advice for firefighters**

**Special protective equipment and precautions 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** Minimize generating airborne mists and vapors. Avoid breathing mist or aerosols. Avoid contact with skin, eyes or clothing. When handling, use appropriate personal protective

# SAFETY DATA SHEET

Product Name Fludarabine Phosphate Injection  
Revision date 16-Jun-2025

Page 5 / 12  
Version 6

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

## General hygiene considerations

### 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.

#### Mannitol

Russia MAC: 10 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	TWA-TMW: 2 mg/m <sup>3</sup> ; inhalable fraction
	STEL-KZGW: 4 mg/m <sup>3</sup> (8 X 5 min); inhalable fraction
Bulgaria	TWA: 2.0 mg/m <sup>3</sup> ; alkaline aerosols
Czech Republic	1 mg/m <sup>3</sup>
	Ceiling: 2 mg/m <sup>3</sup>
Denmark	Ceiling: 2 mg/m <sup>3</sup> ;
Estonia	TWA: 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	TWA-AK: 1 mg/m <sup>3</sup> ;
	STEL-CK: 2 mg/m <sup>3</sup> ;
Ireland	STEL: 2 mg/m <sup>3</sup> ;
Ceiling Limit Value	2 mg/m <sup>3</sup>
Latvia	TWA: 0.5 mg/m <sup>3</sup> ;
Poland	TWA-NDS: 0.5 mg/m <sup>3</sup> ;
	STEL-NDSch: 1 mg/m <sup>3</sup> ;
Romania	TWA: 1 mg/m <sup>3</sup> ;
	STEL: 3 mg/m <sup>3</sup> ;
Slovakia	TWA: 2 mg/m <sup>3</sup> ;
Spain	STEL (VLA-EC): 2 mg/m <sup>3</sup> ;
Switzerland	TWA-MAK: 2 mg/m <sup>3</sup> ; inhalable dust
	STEL-KZGW: 2 mg/m <sup>3</sup> ; inhalable dust
OSHA PEL	TWA: 2 mg/m <sup>3</sup>
	(vacated) Ceiling: 2 mg/m <sup>3</sup>
United Kingdom	STEL: 2 mg/m <sup>3</sup> ;

#### 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

# SAFETY DATA SHEET

Product Name Fludarabine Phosphate Injection  
Revision date 16-Jun-2025

Page 6 / 12  
Version 6

upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

## Fludarabine phosphate

Pfizer Occupational Exposure  
Band (OEB):

OEB 4 (control exposure to the range of 1ug/m<sup>3</sup> to <10ug/m<sup>3</sup>)

## 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.

### 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.).

### Thermal hazards

No information available.

### Environmental exposure controls

No information available.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

#### Physical state

Liquid

#### Color

No information available

#### Odor

No information available.

#### Odor threshold

No information available

#### Property

#### Values

#### Melting point / freezing point

No data available

#### Boiling point or initial boiling point and boiling range

No data available

# SAFETY DATA SHEET

Product Name Fludarabine Phosphate Injection  
Revision date 16-Jun-2025

Page 7 / 12  
Version 6

Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	No data available
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

## 9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

### 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 information available.
------------	---------------------------

### 10.2. Chemical stability

Stability	Stable under normal conditions.
-----------	---------------------------------

#### Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information 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

# SAFETY DATA SHEET

Product Name Fludarabine Phosphate Injection  
Revision date 16-Jun-2025

Page 8 / 12  
Version 6

<b>General Information:</b>	The information included in this section describes the potential hazards of the individual ingredients
<b>Short term</b>	May cause eye and skin irritation (based on components)
<b>Long Term:</b>	Repeat-dose studies in animals have shown a potential to cause adverse effects on male reproductive system, fetus.
<b>Known Clinical Effects:</b>	Bone marrow suppression is the most serious adverse effect seen during clinical use. Adverse effects most commonly reported in clinical use include fever, chills, infection, nausea, vomiting, malaise, tiredness, loss of appetite (anorexia), weakness.
<b>Acute toxicity</b>	Based on available data, the classification criteria are not met.
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Respiratory or skin sensitization</b>	Based on available data, the classification criteria are not met.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	Classification is based on mixture calculation methods based on component data.
<b>Germ cell mutagenicity</b>	Classification is based on mixture calculation methods based on component data.
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.

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

### Mannitol

Rat Oral LD 50 13500 mg/kg  
Mouse Oral LD 50 22 g/kg

### Fludarabine phosphate

Rat Oral LD50 > 2000 mg/kg

### Sodium hydroxide

Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Mannitol	= 13500 mg/kg ( Rat )	-	-
Water	> 90 mL/kg ( Rat )	-	-
Sodium hydroxide	= 325 mg/kg ( Rat )	= 1350 mg/kg ( Rabbit )	-

**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

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

### Fludarabine phosphate

Embryo / Fetal Development Rat Intravenous 10 mg/kg/day LOAEL Teratogenic, Embryotoxicity, Fetotoxicity  
Embryo / Fetal Development Rabbit Intravenous 5 mg/kg/day LOAEL Teratogenic, Embryotoxicity, Fetotoxicity

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

### Fludarabine phosphate

Dominant Lethal Assay Mouse Negative  
*In Vitro* HGPRT Forward Gene Mutation Assay Chinese Hamster Ovary (CHO) cells Negative  
*In Vitro* Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive



# SAFETY DATA SHEET

Product Name Fludarabine Phosphate Injection  
Revision date 16-Jun-2025

Page 9 / 12  
Version 6

Sister Chromatid Exchange Positive  
*In Vivo* Micronucleus Mouse Positive

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

## **11.2. Information on other hazards**

### **11.2.1. Endocrine disrupting properties**

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

### **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**

#### **PBT and vPvB assessment**

Chemical name	PBT and vPvB assessment
Sodium hydroxide	Not PBT/vPvB PBT assessment does not apply

### **12.6. Endocrine disrupting properties**

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

### **12.7. Other adverse effects**

**Other adverse effects** No information available.

**PMT or vPvM properties** Based on available data, the classification criteria are not met.

# SAFETY DATA SHEET

Product Name Fludarabine Phosphate Injection  
Revision date 16-Jun-2025

Page 10 / 12  
Version 6

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

#### Waste from residues/unused products

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

## Section 15: REGULATORY INFORMATION

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

Mannitol

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-711-8
AICS	Present

Fludarabine phosphate

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

Water

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

Sodium hydroxide

CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	1000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	215-185-5
AICS	Present

# SAFETY DATA SHEET

Product Name Fludarabine Phosphate Injection  
Revision date 16-Jun-2025

Page 11 / 12  
Version 6

**Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)**

Schedule 5  
Schedule 6

## National regulations

### Germany

**Chemical Prohibition Ordinance (ChemVerbotsV)**

Not applicable

TRGS 905

Not applicable

### Switzerland

**Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018** Not applicable

**Storage of Hazardous Material**

Not applicable

**WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20**

Not applicable

**Major Accidents Ordinance SR 814.012**

Not applicable

### 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	75	-

### **Persistent Organic Pollutants**

Not applicable

### **Ozone-depleting substances (ODS) Regulation (EU) 2024/590**

Not applicable.

### **Explosives Precursors Marketing and Use (2019/1148)**

Not applicable

#### Legend:

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

**DSL/NDL** - Canadian Domestic Substances List/Non-Domestic Substances List

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

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing Chemicals Inventory

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

**NZIoC** - New Zealand Inventory of Chemicals

**TCSI** - Taiwan Chemical Substance Inventory

# SAFETY DATA SHEET

Product Name Fludarabine Phosphate Injection  
Revision date 16-Jun-2025

Page 12 / 12  
Version 6

## 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 any hazard and/or precautionary statements referred to under Sections 2-15

H360FD - May damage fertility. May damage the unborn child H340 - May cause genetic defects H314 - Causes severe skin burns and eye damage

#### Data Sources:

Publicly available toxicity information.

#### Reason for revision

Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

#### Revision date

16-Jun-2025

#### 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.