

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form	: Substance
Substance name	: Fludarabine phosphate
Chemical name	: Fludarabine phosphate
CAS-No.	: 75607-67-9
Product code	: 201600391

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

##### Relevant identified uses

Use of the substance/mixture	: Scientific research and development Technical testing and analysis For professional use only
Function or use category	: Laboratory chemicals

##### Uses advised against

Restrictions on use	: Not for food, drug or home use
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#### 1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare  
EDQM, Council of Europe  
7, Allée Kastner, CS30026  
F 67081 Strasbourg  
France  
T +33(0)388412035, F +33(0)388412771  
[sds@edqm.eu](mailto:sds@edqm.eu), [www.edqm.eu](http://www.edqm.eu)

#### 1.4. Emergency telephone number

Emergency number	: +33(0)390215608
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### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Germ cell mutagenicity, Category 2	H341
Carcinogenicity, Category 2	H351
Reproductive toxicity, Category 1B	H360Df
Specific target organ toxicity – Repeated exposure, Category 1	H372
Full text of H- and EUH-statements: see section 16	

##### Adverse physicochemical, human health and environmental effects

Suspected of causing cancer. Suspected of causing genetic defects. May damage the unborn child. Suspected of damaging fertility. Causes damage to organs through prolonged or repeated exposure.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS08

Signal word (CLP)	: Danger
Hazard statements (CLP)	: H341 - Suspected of causing genetic defects. H351 - Suspected of causing cancer.

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Precautionary statements (CLP)

- H360Df - May damage the unborn child. Suspected of damaging fertility.  
H372 - Causes damage to organs (bone marrow) through prolonged or repeated exposure.
- : P201 - Obtain special instructions before use.  
P202 - Do not handle until all safety precautions have been read and understood.  
P260 - Do not breathe dust/fume/gas/mist/vapours/spray.  
P264 - Wash hands, forearms and face thoroughly after handling.  
P270 - Do not eat, drink or smoke when using this product.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
P314 - Get medical advice/attention if you feel unwell.  
P405 - Store locked up.  
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

Hazard pictograms (CLP)



GHS08

### 2.3. Other hazards

Other information

- : Active substance (in pharmaceutical products).  
Warning - substance not yet tested completely.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Fludarabine phosphate	CAS-No.: 75607-67-9	≤ 100	Muta. 2, H341 Carc. 2, H351 Repr. 1B, H360Df STOT RE 1, H372

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

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

- First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.
- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- First-aid measures after eye contact : Rinse with water while holding the eyes wide open. Obtain medical attention if pain, blinking or redness persists.
- First-aid measures after ingestion : Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.

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

No additional information available

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

No additional information available

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### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.
- Unsuitable extinguishing media : Do not use a heavy water stream.

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

- Hazardous decomposition products in case of fire : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.

#### 5.3. Advice for firefighters

- Firefighting instructions : Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Avoid contact with skin, eyes and clothing.

##### For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

##### For emergency responders

- Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

#### 6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

#### 6.3. Methods and material for containment and cleaning up

- For containment : Absorb with an inert material and place in an appropriate waste disposal container.
- Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

#### 6.4. Reference to other sections

See Section 13 for disposal information.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

- Additional hazards when processed : Do not expose pregnant or breastfeeding women.
- Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.
- Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

#### 7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.
- Packaging materials : Keep in original containers.

#### 7.3. Specific end use(s)

No additional information available

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### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

No additional information available

#### 8.2. Exposure controls

##### Appropriate engineering controls

##### Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

##### Personal protection equipment

##### Eye and face protection

##### Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

##### Skin protection

##### Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

##### Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

##### Respiratory protection

##### Respiratory protection:

In case of dust formation use respirator with filter: P3

### SECTION 9: Physical and chemical properties

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

Physical state	: Solid
Colour	: white, whitish.
Appearance	: Crystalline powder.
Molecular mass	: 365.2 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: 195 – 202 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 1 – 10 g/l
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

#### 9.2. Other information

No additional information available

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### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

No additional information available

#### 10.2. Chemical stability

No additional information available

#### 10.3. Possibility of hazardous reactions

No additional information available

#### 10.4. Conditions to avoid

No additional information available

#### 10.5. Incompatible materials

No additional information available

#### 10.6. Hazardous decomposition products

No additional information available

### SECTION 11: Toxicological information

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

Acute toxicity (oral)	: Not classified (Lack of data)
Acute toxicity (dermal)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)
Skin corrosion/irritation	: Not classified (Lack of data)
Serious eye damage/irritation	: Not classified (Lack of data)
Respiratory or skin sensitisation	: Not classified (Lack of data)
Germ cell mutagenicity	: Suspected of causing genetic defects.
Carcinogenicity	: Suspected of causing cancer.
Reproductive toxicity	: May damage the unborn child. Suspected of damaging fertility.
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Causes damage to organs (bone marrow) through prolonged or repeated exposure.
Aspiration hazard	: Not classified (Lack of data)

#### 11.2. Information on other hazards

No additional information available

### SECTION 12: Ecological information

#### 12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute)	: Not classified (Lack of data)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Lack of data)

#### 12.2. Persistence and degradability

##### Fludarabine phosphate (75607-67-9)

Persistence and degradability	Rapidly degradable
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#### 12.3. Bioaccumulative potential

No additional information available

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### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

No additional information available

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
<b>14.1. UN number or ID number</b>		
Not applicable	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>		
Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>		
Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>		
Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>		
Not applicable	Not applicable	Not applicable
No supplementary information available		

### 14.6. Special precautions for user

#### Overland transport

Not applicable

#### Transport by sea

Not applicable

#### Air transport

Not applicable

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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### SECTION 15: Regulatory information

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

##### EU-Regulations

###### REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

###### REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

###### REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

###### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

###### Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

###### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

###### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

#### 15.2. Chemical safety assessment

No additional information available

### SECTION 16: Other information

Indication of changes		
Section	Changed item	Comments
	Revision date	<b>Added</b>
	Supersedes version of	<b>Added</b>
1.1	CAS-No.	<b>Added</b>
1.2	Main use category	<b>Removed</b>
1.2	Use of the substance/mixture	<b>Modified</b>
1.2	Restrictions on use	<b>Modified</b>
2.1	Adverse physicochemical, human health and environmental effects	<b>Modified</b>
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	<b>Modified</b>
2.2	Hazard statements (CLP)	<b>Modified</b>
2.2	Signal word (CLP)	<b>Modified</b>
2.2	Precautionary statements (CLP)	<b>Modified</b>
2.3	Other information	<b>Added</b>
4.1	First-aid measures after eye contact	<b>Modified</b>
4.1	First-aid measures after skin contact	<b>Modified</b>
4.1	First-aid measures after ingestion	<b>Added</b>

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Indication of changes		
Section	Changed item	Comments
4.1	First-aid measures after inhalation	<b>Added</b>
4.1	First-aid measures general	<b>Added</b>
5.1	Suitable extinguishing media	<b>Modified</b>
5.1	Unsuitable extinguishing media	<b>Added</b>
5.2	Fire hazard	<b>Removed</b>
5.2	Hazardous decomposition products in case of fire	<b>Added</b>
5.3	Firefighting instructions	<b>Modified</b>
5.3	Protection during firefighting	<b>Added</b>
6.1	Emergency procedures	<b>Modified</b>
6.1	General measures	<b>Added</b>
6.1	Protective equipment	<b>Added</b>
6.2	Environmental precautions	<b>Added</b>
6.3	Methods for cleaning up	<b>Added</b>
6.3	For containment	<b>Added</b>
6.4	Reference to other sections (8, 13)	<b>Added</b>
7.1	Hygiene measures	<b>Added</b>
7.1	Precautions for safe handling	<b>Added</b>
7.1	Additional hazards when processed	<b>Added</b>
7.2	Storage conditions	<b>Added</b>
7.2	Packaging materials	<b>Added</b>
7.3	Specific end uses	<b>Removed</b>
8.2	Skin and body protection	<b>Modified</b>
8.2	Appropriate engineering controls	<b>Modified</b>
8.2	Hand protection	<b>Modified</b>
8.2	Eye protection	<b>Added</b>
8.2	Respiratory protection	<b>Added</b>
9	Molecular mass	<b>Added</b>
9	Melting point	<b>Added</b>
9	Colour	<b>Added</b>
9	Appearance	<b>Added</b>
10.1	Reactivity	<b>Removed</b>
10.3	Possibility of hazardous reactions	<b>Removed</b>
10.5	Incompatible materials	<b>Removed</b>
10.6	Hazardous decomposition products	<b>Removed</b>
12.1	Ecology - general	<b>Removed</b>



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Full text of H- and EUH-statements:	
Carc. 2	Carcinogenicity, Category 2
H341	Suspected of causing genetic defects.
H351	Suspected of causing cancer.
H360Df	May damage the unborn child. Suspected of damaging fertility.
H372	Causes damage to organs (bone marrow) through prolonged or repeated exposure.
Muta. 2	Germ cell mutagenicity, Category 2
Repr. 1B	Reproductive toxicity, Category 1B
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1

Safety Data Sheet (SDS), EU

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