according to UK REACH Regulation

## Fludarabine standard

Revision date: 27.04.2022

Product code: 2934

Page 1 of 5

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

## 1.1. Product identifier

Fludarabine standard

### Further trade names

2-Fluoro-9-ß-Darabinofuranosyladenine

Synonymes:

Adenine, 9-ß-D-arabinofuranosyl-2-fluoro- (8CI); 9-ß-DArabinofuranosyl-2-fluoro-9Hpurin-

6-amine; 2-Fluoro Ara-A; 2-Fluoroadenine arabinoside; 2F-Ara-A; 9-ß-D-Arabinofuranosyl-2-fluoroadenine; 9-ß-

D-Arabinosyl-2-fluoroadenine; F-ara-A; Fludarabine; NSC 118218; NSC 118218H CAS No: 21679-14-1 EC No: 244-525-5

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

### Use of the substance/mixture

Fludarabine standard may be used as reference standard for [18F]Fludarabine

#### 1.3. Details of the supplier of the safety data sheet

Company name:	ABX advanced biochemical com	pounds
	Biomedizinische Forschungsrea	genzien GmbH
Street:	Heinrich-Gläser-Straße 10-14	
Place:	01454 Radeberg	
Telephone:	+49 3528 4041 60	Telefax: +49 3528 4041 65
e-mail:	info@abx.de	
Contact person:	Dr. Christoph Meyer	Telephone: +49 3528 4041 8732
e-mail:	meyer@abx.de	
Internet:	http://www.abx.de	
1.4. Emergency telephone	+49 3528 4041 60	
www.wahaaw		

## number:

**SECTION 2: Hazards identification** 

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

GB CLP Regulation

Acute Tox. 4; H302

Full text of hazard statements: see SECTION 16.

## 2.2. Label elements

**Pictograms:** 

**GB CLP Regulation** 

Signal word:

Warning



#### Hazard statements

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

#### **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapours/spray.

P261

## according to UK REACH Regulation

Fludarabine standard			
Revision date: 27.04.2022	Product code: 2934	Page 2 of 5	
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.		
P302+P352	IF ON SKIN: Wash with plenty of water.		
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.		
P403+P233	Store in a well-ventilated place. Keep container tightly closed.		

#### **SECTION 3: Composition/information on ingredients**

#### 3.1. Substances

Sum formula:	C10H12FN5O4
Molecular weight:	285.23

## Hazardous components

CAS No	Chemical name		Quantity	
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
21679-14-1	Fludarabin standard		95 - < 100 %	
	244-525-5			
	Acute Tox. 4; H302			

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

Specific Conc. Limits, M-factors and ATE			
CAS No	EC No	Chemical name	Quantity
	Specific Conc. L	imits, M-factors and ATE	
21679-14-1	244-525-5	Fludarabin standard	95 - < 100 %
	oral: ATE = 500	) mg/kg	

## **SECTION 4: First aid measures**

#### 4.1. Description of first aid measures

#### After inhalation

Provide fresh air. Medical treatment necessary.

#### After contact with skin

After contact with skin, wash immediately with: Water. Change contaminated clothing.

#### After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

## After ingestion

If swallowed, immediately drink: Water. Medical treatment necessary.

## **SECTION 5: Firefighting measures**

## 5.1. Extinguishing media

## Suitable extinguishing media

Foam. Extinguishing powder. Atomized water. Carbon dioxide (CO2).

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

In case of fire and/or explosion do not breathe fumes.

#### 5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

## Additional information

Suppress gases/vapours/mists with water spray jet. Contaminated fire-fighting water must be collected separately. Do not allow to enter into surface water or drains.

## according to UK REACH Regulation

# Fludarabine standard

Revision date: 27.04.2022

Product code: 2934

Page 3 of 5

## **SECTION 6: Accidental release measures**

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

#### General advice

Provide adequate ventilation. Avoid dust formation. Do not breathe dust. Avoid contact with skin, eyes and clothes.

#### 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

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

### Other information

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal. Clear contaminated areas thoroughly.

## **SECTION 7: Handling and storage**

#### 7.1. Precautions for safe handling

#### Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe dust. When using do not eat, drink, smoke, sniff.

#### Advice on general occupational hygiene

Remove contaminated, saturated clothing immediately. Protect skin by using skin protective cream. After work, wash hands and face. When using do not eat or drink.

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

## Requirements for storage rooms and vessels

Keep container dry. Keep the packing dry and well sealed to prevent contamination and absorbtion of humidity.

#### Further information on storage conditions

storage temperature 2-8 °C Protect against: Light Keep under argon.

#### **SECTION 8: Exposure controls/personal protection**

## 8.1. Control parameters

## Additional advice on limit values

To date, no national critical limit values exist.

## 8.2. Exposure controls

#### Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe dust.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Tightly sealed safety glasses.

#### Hand protection

Single-use gloves. NBR (Nitrile rubber).

#### Skin protection

Lab apron. Chemical resistant safety shoes.

## according to UK REACH Regulation

Revision date: 27.04.2022	Product code: 29	934		Page 4 of \$
SECTION 9: Physical and ch	emical properties			
0.1. Information on basic physic	cal and chemical properties			
Physical state:	solid			
Colour:	whitish			
Odour:	odourless			
			Test method	
Changes in the physical stat	te			
Water solubility:		Yes.	OECD 105	
Solubility in other solvents				
Dimethylsulfoxide (DMSO	) Dimethylformamide Ethanol			
Bulk density:			ISO 1183 (A)	

## **SECTION 11: Toxicological information**

### 11.1. Information on hazard classes as defined in GB CLP Regulation

#### Acute toxicity

CAS No	Chemical name				
	Exposure route Dose Species Source Method		Method		
21679-14-1	Fludarabin standard				
		ATE 500 mg/kg			

## Irritation and corrosivity

Irritating to eyes. Following inhalation: Lung irritation. Coughing. shortage of breath. After skin contact: irritant.

#### Additional information on tests

The classification was carried out according to the calculation method of the Preparations Directive (1999/45/EC).

## **SECTION 12: Ecological information**

## 12.1. Toxicity

There are no data available on the mixture itself.

## 12.5. Results of PBT and vPvB assessment

This substance does not meet the PBT/vPvB criteria of UK REACH.

#### 12.6. Endocrine disrupting properties

This substance does not have endocrine disrupting properties with respect to non-target organisms.

#### **Further information**

Do not allow to enter into surface water or drains.

## **SECTION 13: Disposal considerations**

#### 13.1. Waste treatment methods

### Disposal recommendations

Dispose of waste according to applicable legislation.

## List of Wastes Code - residues/unused products

## according to UK REACH Regulation

	Fludarabine standard	
Revision date: 27	Y.04.2022 Product code: 2934	Page 5 of 5
160508	WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded organic chemicals consisting of or containing hazardous substances; hazardous waste	
List of Waste 160508	s Code - used product WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded organic chemicals consisting of or containing hazardous substances; hazardous waste	
List of Waste 150110	s Code - contaminated packaging WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste	
Contaminate Non-conta substance	minated packages may be recycled. Handle contaminated packages in the same way as the	
SECTION 14: T	ransport information	
Other applicable No dange	<b>information</b> rous good in sense of these transport regulations.	
SECTION 15: R	legulatory information	
15.1 Safoty hoa	Ith and environmental regulations/legislation specific for the substance or mixture	

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

## National regulatory information

Water hazard class (D):

3 - highly hazardous to water

# **SECTION 16: Other information**

## Relevant H and EUH statements (number and full text)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.