According to Regulation (EC) No. 1907/2006

Version 2.0 Revision date: 14.11.2014

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

1.1 Product identifiers

Product name: FASTlab PET Fluciclovine Cassette 1x1

Synonym: No synonyms

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

Identified use: The FASTlab PET Fluciclovine Cassette 1x1 is a single use, disposable fluid path containing reagents and auxiliary materials required for the synthesis of Fluciclovine (^{18}F) Injection using the FASTlab™ Synthesizer.

Uses advised against: Any other than the identified use.

1.3 Details of the supplier of the safety data sheet

Company: GE Healthcare AS, Nycoveien 1-2, P.O. Box 4220 Torshov, N-0401, OSLO, Norway

Telephone: +47 23185050

Fax: +47 23186000

E-mail address: MSDS@ge.com

1.4 Emergency phone number: +47 22 59 13 00 (National Poison Centre in Norway)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to regulation (EC) No 1272/2008

Flammable liquids, (Category 2), H225
Acute toxicity, Oral, (Category 4), H302
Acute toxicity, Dermal, (Category 4), H312
Skin corrosion, (Category 1A), H 314
Skin irritation, (Category 2), H315
Eye irritation, (Category 2), H319
Acute toxicity, Inhalation, (Category 4), H332

For the full text of the H-statements mentioned in this section, see Section 16.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

Hazard pictograms

Signal word Danger

Hazard statements

H225	Highly flammable liquid and vapour
H302	Harmful if swallowed
H319	Causes serious eye irritation
H314	Causes severe skin burns and eye corrosion
H332	Harmful if inhaled
H335	May cause respiratory irritation

Precautionary statements

P210	Keep away from heat/sparks/open flames/hot surfaces – No smoking
P261	Avoid breathing dust/ fume/gas/mist/vapours/spray
P281	Use personal protective equipment as required
P302 + P352	IF ON SKIN: Wash with plenty of soap and water
P305 + P351 + P338	IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing
P310	Immediately call a POISON CENTER or doctor/physician

Supplemental Hazard Information None

2.3 Other hazards

The chemicals do not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex II.

SECTION 3: Composition/Information on ingredients

3.2 Mixtures

Synonyms None

Component	Classification according to Regulation (EC) No 1278/2008 (CLP)	Concen-tration	Volume
Acetonitrile			
CAS No 75-05-8 EC No 200-835-2 Index No 608-001-00-3	Flam. Liq. 2; Acute Tox. 4; Eye Irrit. 2; H225, H302 + H312 + H332, H319	<= 100 %	4.1 ml
Hydrochloric acid			
CAS No 7647-01-0 EC No 231-595 7 Index No 017-002-01-X	Skin Irrit. 2; Eye Irrit. 2; STOT SE 3; H315, H319, H335	12.33 % (4 M)	2 ml
Sodium hydroxide			
CAS No 1310-73-2 EC No 215-185-5 Index No 011-002-00-6	Skin Corr. 1A; H314	7.58 % (2 M)	4.1 ml

For the full text of the H statements mentioned in this section, see Section 16.

Under normal conditions of handling the chemicals are not accessible. If the package or the cassette is damaged handle as described in Section 6 below.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice
Consult a physician. Show this safety data sheet to the doctor/physician in attendance.

Following inhalation
If breathed in, move person into fresh air. If necessary, give artificial respiration. Consult a physician.

Following skin contact
Take off contaminated clothing and shoes immediately. Wash thoroughly with soap and plenty of water. Consult a physician.

Following eye contact
Rinse thoroughly with plenty of water for at least 15 minutes with eyelid held open. Consult a physician.

Following ingestion
Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a doctor/physician.

4.2 Most important symptoms and effects, both acute and delayed
The most important known symptoms and effects are described in the labelling (see Section 2.2) and in Section 11.

4.3 Indication of any immediate medical attention and special treatment needed
No data available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media
Use water spray, carbon dioxide (CO_2), foam or dry powder.

Unsuitable extinguishing media
For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture
Combustible
Some of the possible vapours are heavier than air and may spread along floors.
Development of hazardous combustion gases or vapours possible in the event of fire.

5.3 Advice for firefighters
Stay in the danger area only with self-contained breathing apparatus. Prevent skin contact by wearing suitable protective equipment for firefighting.

SECTION 6: Accidental release measures

6.1 Personal precautions, protection equipment and emergency procedures

Advice for non-emergency personnel: If the cassette is damaged, avoid contact with the chemicals, avoid breathing dust, vapours, aerosols or mists and wear protective clothing, eye/face protection and gloves. Ensure adequate ventilation. Remove all sources of ignition.

Advice for emergency responders: For personal protection see Section 8.

6.2 Environmental precautions
Do not empty chemicals into drains.

6.3 Methods and material for containment and cleaning up
Take up with liquid-absorbent material (e.g. Chemizorb®). Neutralize if required. Dispose of properly. Clean up affected area.

6.4 Reference to other sections
For disposal see Section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Protective measures:
The chemicals are stored in glass or polypropylene vials within the cassette manifold and, during transport and storage, in an outer protective clamshell. As such the cassette is very robust. Follow accidental release measures as described in Section 6 if any of the vials are broken. Observe label precautions.

Measures to prevent fire:
Keep away from open flames, hot surfaces and sources of ignition.

7.2 Conditions for safe storage
Store in original cardboard packaging at +2 to +30°C.

7.3 Specific end use
The FASTlab PET Fluciclovine Cassette 1x1 is a single use, disposable fluid path containing reagents and auxiliary materials required for the synthesis of Fluciclovine (^{18}F) Injection using the FASTlab™ synthesizer. Only to be used for this purpose by trained personnel in a dedicated hospital environment.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Components with workplace control parameters
Not applicable. The object is an article/container with chemical substances/mixture and remains an enclosed system throughout its lifetime. For the undamaged cassette there is no workplace exposure.

8.2 Exposure controls

Appropriate engineering controls

The intact cassette and its identified use involves an enclosed process and does not give rise to chemical exposure. Additional engineering controls not required.

Personal protective equipment

Eye protection: Safety glasses required. If damaged cassette and spills wear chemical splash goggles.

Hand protection: Not required if the cassette is undamaged. Avoid contact with the chemicals; wear hand protection if the cassette is damaged.

Protective clothing: Not required if the cassette is undamaged. Wear protective clothing if the cassette is damaged.

Environmental exposure controls: Do not empty into drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

	Acetonitrile	**Hydrochloric acid**	**Sodium hydroxide**
Form	Liquid	Liquid	Liquid
Colour	Colourless	Colourless	Colourless
Odour	Etherlike	Stinging	No data
Odour threshold	39.8 ppm	0.8-5 ppm	No data
pH	No data	< 1 at 20 ^{o} C	14.0 strongly basic
Melting point/freezing point	-45.7 ^{o}C	-30 ^{o}C	-12 – 10 ^{o}C
Initial boiling point and boiling range	81.6 ^{o}C at 1,013 hPa	No data	105 - 140 ^{o}C
Flash point	2 ^{o}C Method: c.c.	Not applicable	Not applicable
Evaporation rate	No data	No data	No data

	Acetonitrile	Hydrochloric acid	Sodium hydroxide
Flammability (solid, gas)	No data	Not applicable	Not applicable
Lower explosion limit	3.0 %(V)	Not applicable	Not applicable
Upper explosion limit	17 %(V)	Not applicable	Not applicable
Vapour pressure	97 hPa at 20 ^{o}C	190 hPa 20 ^{o}C	< 24 hPa 20 ^{o}C
Relative vapour density	1.42	No data	1.38
Relative density	0.786 g/cm^3 at 20 ^{o}C	1.19 g/cm^3 at 20 ^{o}C	1.08 g/cm^3 at 20 ^{o}C
Water Solubility	At 20 ^{o}C: Soluble	At 20 ^{o}C: Soluble	Completely miscible
Partitition coefficient: n-octanol/water	log Pow -0.34	No data	No data
Auto ignition temperature	No data	No data	No data
Viscosity, dynamic	0.316 mPa.s at 25 ^{o}C	2.3 mPa.s at 15 ^{o}C	No data
Explosive properties	Not classified as explosive	Not classified as explosive	Not classified as explosive
Oxidising properties	None	None	No data

9.2 Other safety information

Minimum ignition energy	524 ^{o}C	Not applicable	Not applicable
Corrosion	No	May be corrosive to metals	May be corrosive to metals

SECTION 10: Stability and reactivity

10.1 Reactivity

Contains small amounts of hydrochloric acid and sodium hydroxide. This has been shown by experiment to cause no problem when mixed.

10.2 Chemical stability
Stable under normal storage and transport conditions.

10.3 Possibility of hazardous reactions
Not applicable, enclosed system.

10.4 Conditions to avoid
Warming.

10.5 Incompatible materials
Not applicable, enclosed system.

10.6 Hazardous decomposition products
In the event of fire: See Section 5.

SECTION 11: Toxicological information

	Acetonitrile	**Hydrochloric acid 4M**	**Sodium hydroxide 2M**
LD50(O)rat	2.46-6.5 g/kg	Not known	Not known
Skin contact	Slight irritation	Corrosive to skin Burns at prolonged exposure	Corrosive to skin Burns, necrosis
Inhalation	Slight irritation	Respiratory tract irritation	Burns of the respiratory tract
Eye contact	Irritation	Highly corrosive	Severe corrosion and eye damage
Ingestion	Headache, dizziness, nausea	Highly corrosive	Severe burns, tissue perforations

The product should be handled with the care usual when dealing with chemicals

SECTION 12: Ecological information

12.1 Do not allow to enter water and soil.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

The used cassette is considered to be radioactive waste and needs to decay sufficiently before disposal. Then dispose of the unopened cassette as hazardous waste.

SECTION 14: Transport information

		Acetonitrile	**Hydrochloric acid**	**Sodium hydroxide**
14.1	UN number	UN 1648	UN 1789	UN 1824
14.2	UN proper shipping name	ACETONITRILE	HYDROCHLORIC ACID	SODIUM HYDROXIDE SOLUTION
14.3	Transport hazard class	3	8	8
14.4	Packing group	II	II	II
14.5	Environmental hazards	--	--	--
14.6	Special precautions for user	Not relevant for this article		
14.7	Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code			Not relevant for this article

SECTION 15: Regulatory information

15.1 The cassette is not subject to registration as it should be regarded as a combination of an article (manifold, filters and tubing) and a substance/mixture. Justification by using the procedure outlined in ECHA Guidance on requirements for substances in articles, Version 2, relating to the REACH Regulation (EC) No 1907/2006.

15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier

SECTION 16: Other information

Full text of H-Statements referred to under Sections 2 and 3

H225	Highly flammable liquid and vapour
H290	May be corrosive to metals
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation

Training advice Provide adequate information, instruction and training for operators.

Abbreviations and acronyms

Flam. Liq.	flammable liquid
Irrit.	irritant
LD50(O)rat	oral lethal dose, 50%, rat
PBT	persistent, bioaccumulative and toxic
Tox.	toxicity
vPvB	very persistent and very bioaccumulative