

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 Flutemetamol Cassette 1x1
Synonym: No synonyms

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

Identified use: The FASTlab PET Flutemetamol Cassette 1x1 is a single use, disposable fluid path containing reagents and auxiliary materials required for the synthesis of 18F Flutemetamol using the FASTlab™ synthesiser.

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 3), H301

Acute toxicity, Oral, (Category 4), H302

Acute toxicity, Dermal, (Category 3), H311

Acute toxicity, Dermal, (Category 4), H 312

Skin irritation, (Category 2), H315
Eye irritation; (Category 2), H319
Acute toxicity, Inhalation, (Category 3), H331
Acute toxicity, Inhalation, (Category 4), H332
Specific target organ toxicity – Single exposure, Respiratory system, (Category) 3, H335
Specific target organ toxicity – single exposure, (Category 1), H370

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
H301	Toxic if swallowed
H311	Toxic in contact with skin
H315	Causes skin irritation
H319	Causes serious eye irritation
H331	Toxic if inhaled
H370	Causes damage to organs

Precautionary statements

P210	Keep away from heat/sparks/open flames/hot surfaces – No smoking
P260	Do not breathe dust/fume/gas/mist/vapours/spray
P281	Use personal protective equipment as required
P301 + P331	IF SWALLOWED: immediately call a POISON CENTER or doctor/physician
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

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)	Concentration	% weight of mixture
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 %	53
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)	5,8
Ethanol			
CAS No 64-17-5 EC No 200-578-6 Index No 603-002-00-5	Flam. Liq. 2; H225	<= 100 %	5,7
Methanol			
CAS No 67-56-1 EC No 200-659-6 Index No 603-001-00-X	Flam. Liq. 2, Acute Tox. 3, STOT SE 1; H225, H301, H311, H331, H370	<= 100%	5,6

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

Wash thoroughly with soap and plenty of water. Remove any contaminated clothing. Consult a physician if necessary.

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 (CO₂), 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. Use special 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 vapours, aerosols or mists and wear protective clothing, eye 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, 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 Flutemetamol Cassette 1x1 is a single use, disposable fluid path containing reagents and auxiliary materials required for the synthesis of ^{18}F Flutemetamol 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	Ethanol	Methanol
Form	Liquid	Liquid	Liquid	Liquid



	Acetonitrile	Hydrochloric acid	Ethanol	Methanol
Colour	Colourless	Colourless	Colourless	Colourless
Odour	Etherlike	Stinging	Alcohol-like	Pungent
Odour threshold	39.8 ppm	0,8-5 ppm	0,1-5058,5 ppm	No data
pH	No data	< 1 at 20 °C	No data	No data
Melting point/freezing point	-45,7 °C	-30 °C	-114,5 °C	-98 °C
Initial boiling point and boiling range	81,6 °C at 1,013 hPa	No data	78,3 °C at 1,013 hPa	64,7 °C
Flash point	2 °C Method: c.c.	Not applicable	12 °C Method: c.c.	9,7 °C Closed cup
Evaporation rate	No data	No data	No data	No data
Flammability (solid, gas)	No data	Not applicable	No data	No data
Lower explosion limit	3,0 %(V)	Not applicable	3,5 %(V)	6 %(V)
Upper explosion limit	17 %(V)	Not applicable	15 %(V)	36 %(V)
Vapour pressure	97 hPa at 20 °C	190 hPa at 20 °C	59 hPa at 20 °C	130,3 hPa at 20 °C
Relative vapour density	1,42	No data	1,6	1,11
Relative density	0,786 g/cm ³ at 20 °C	1,19 g/cm ³ at 20 °C	0,790 g/cm ³ at 20 °C	0,791 g/mL at 25 °C
Water Solubility	At 20 °C Soluble	At 20 °C Soluble	At 20 °C Completely miscible	Completely miscible
Partition coefficient: n-octanol/water	log Pow -0,34	No data	log Pow -0,31	log Pow -0,77
Auto ignition temperature	No data	No data	No data	455 °C at 1,013 hPa



	Acetonitrile	Hydrochloric acid	Ethanol	Methanol
Viscosity, dynamic	0,316 mPa.s at 25 °C	2,3 mPa.s at 15 °C	1,2 mPa.s at 20 °C	No data
Explosive properties	Not classified as explosive	Not classified as explosive	Not classified as explosive	Not classified as explosive
Oxidising properties	None	None	None	None

9.2 Other safety information

Minimum ignition energy	524 °C	Not applicable	425 °C	0,14 mJ
Corrosion	No	May be corrosive to metals	No	No

SECTION 10: Stability and reactivity

10.1 Reactivity

Contains small amounts of hydrochloric acid. 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	Ethanol	Methanol
LD50(O)rat	2,46-6,5 g/kg	Not known	6,2 g/kg	1,2-2,8 g/kg
Skin contact	Slight irritation	Corrosive to skin Burns at prolonged exposure	Slight irritation	Slight irritation
Inhalation	Slight irritation	Respiratory tract irritation	Slight irritation	Slight irritation
Eye contact	Irritation	Highly corrosive	Irritation	Irritation
Ingestion	Headache, dizziness, nausea	Highly corrosive	Euphoria dizziness	Headache, dizziness, drowsiness, coma

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	Ethanol	Methanol
14.1 UN number	UN 1648	UN 1789	UN 1170	UN 1230
14.2 UN proper shipping name	ACETONITRILE	HYDROCHLORIC ACID	ETHANOL	METHANOL

		Acetonitrile	Hydrochloric acid	Ethanol	Methanol
14.3	Transport hazard class	3	8	3	3
14.4	Packing group	II	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
H301	Toxic if swallowed
H302	Harmful if swallowed
H311	Toxic in contact with skin
H312	Harmful in contact with skin
H315	Causes skin irritation
H319	Causes serious eye irritation
H331	Toxic if inhaled
H332	Harmful if inhaled
H335	May cause respiratory irritation
H370	Causes damage to organs

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



Abbreviations and acronyms

Cat.	category
Irrit.	irritant
LD50(O)rat	oral lethal dose, 50%, rat
PBT	persistent, bioaccumulative and toxic
STOT SE	specific target organ toxicity, single exposure
Tox.	toxicity
vPvB	very persistent and very bioaccumulative