



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Amyvid™</b>	
<b>Other means of identification</b>		
<b>Synonyms</b>	18F-AV-45 * Florbetapir F 18 Injection	
<b>Recommended use</b>	Radioactive diagnostic agent for Positron Emission Tomography (PET) imaging.	
<b>Recommended restrictions</b>	None known.	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Manufacturer</b>		
<b>Company name</b>	Eli Lilly and Company	
<b>Address</b>	Lilly Corporate Center Indianapolis, IN 46285 United States	
<b>Telephone</b>	Phone:	+1-317-276-2000
<b>E-mail</b>	lilly_msds@lilly.com	
<b>Emergency phone number</b>	CHEMTREC:	+1-800-424-9300
<b>LY Number</b>	LY3078786	

## 2. Hazard(s) identification

<b>Physical hazards</b>	Flammable liquids	Category 3
<b>Health hazards</b>	Not classified.	
<b>OSHA defined hazards</b>	Not classified.	

### Label elements



<b>Signal word</b>	Warning
<b>Hazard statement</b>	
H226	Flammable liquid and vapor.

### Precautionary statement

#### Prevention

P210	Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P233	Keep container tightly closed.
P241	Use explosion-proof electrical/ventilating/lighting equipment.
P242	Use only non-sparking tools.
P243	Take precautionary measures against static discharge.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

#### Response

P303 + P361 + P353	IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P370 + P378	In case of fire: Use appropriate media to extinguish.

#### Storage

P403 + P235	Store in a well-ventilated place. Keep cool.
-------------	--

#### Disposal

P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
------	---

**Hazard(s) not otherwise classified (HNOC)** RADIOACTIVE.

## Supplemental information

This product is a radioactive diagnostic imaging agent containing Fluorine-18 and should be handled with appropriate safety measures to minimize radiation exposure during transport, storage, emergencies and administration. Radiopharmaceuticals should only be administered to humans under the control of physicians who are qualified by specific training and experience in the safe use and handling of radioactive materials, and whose experience and training have been approved by the appropriate governmental agency authorized to license the administration of radiopharmaceuticals.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
F-18		N/A	< 1
Ethanol		64-17-5	10

### Composition comments

\* Note: The exact concentration of Florbetapir F-18 is unknown as the radioactive element Fluorine-18 has a 109 minute half-life and will decay quickly.

Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

## 4. First-aid measures

### Inhalation

If symptoms develop move victim to fresh air. If symptoms persist, get medical attention.

### Skin contact

Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

### Eye contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If eye irritation persists: Get medical advice/attention.

### Ingestion

IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

### Most important symptoms/effects, acute and delayed

CAUTION: RADIOACTIVE. May cause temporary irritation on skin or eye contact. Ingestion of this product may result in central nervous system effects including headache, sleepiness, dizziness, slurred speech and blurred vision. Prolonged exposure may cause chronic effects.

### General information

IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician. Contact radiation safety personnel to survey for effectiveness of decontamination.

## 5. Fire-fighting measures

### Suitable extinguishing media

Use water fog, alcohol-resistant foam, dry chemical or carbon dioxide (CO<sub>2</sub>) to extinguish flames.

### Unsuitable extinguishing media

None known.

### Specific hazards arising from the chemical

Liquid and vapors are flammable. Vapors may travel considerable distance to a source of ignition and flash back. Hazardous combustion products: Carbon oxides (CO<sub>x</sub>)

### Special protective equipment and precautions for firefighters

Firefighters should wear full protective clothing including self contained breathing apparatus.

### Fire fighting equipment/instructions

Keep run-off water out of sewers and water sources. Dike for water control.

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

Remove sources of ignition. Ventilate well, avoid breathing vapors. Use approved respirator if air contamination is above accepted level. Wear appropriate personal protective equipment.

### Methods and materials for containment and cleaning up

DO NOT CLEAN-UP OR DISPOSE OF, EXCEPT UNDER SUPERVISION OF A SPECIALIST. Use only non-sparking tools. Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container.

### Environmental precautions

Prevent further leakage or spillage if safe to do so. Avoid release to the environment.

## 7. Handling and storage

### Precautions for safe handling

Avoid exposure - obtain special instructions before use. Do not get in eyes, on skin, on clothing. Avoid heat, sparks, open flames and other ignition sources. Wash thoroughly after handling.

Radioactive material must be handled by qualified personnel in conformity with regulations appropriate to the government agency authorized to license the use of this radionuclide.

**Conditions for safe storage, including any incompatibilities**

Store in shielded locations. Storage temperature: between 15 C and 30 C. Keep away from heat, sparks and open flame. Keep locked up or in an area accessible only to qualified or authorized persons. Keep only in the original container.

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### US. ACGIH Threshold Limit Values

Components	Type	Value
Ethanol (CAS 64-17-5)	STEL	1000 ppm

#### US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
Ethanol (CAS 64-17-5)	PEL	1900 mg/m3 1000 ppm

#### US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Ethanol (CAS 64-17-5)	TWA	1900 mg/m3 1000 ppm

### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Appropriate engineering controls

Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. During patient administration, use effective shielding, including lead-glass syringe shields when handling.

The following are recommended for manufacturing or other situations where exposure to contents may occur.

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

#### Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

#### Skin protection

##### Hand protection

Use impervious gloves.

##### Other

Chemical-resistant gloves and impermeable body covering to minimize skin contact.

#### Respiratory protection

None under normal conditions. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn.

#### Thermal hazards

Not available.

## 9. Physical and chemical properties

### Appearance

Liquid

### Physical state

Liquid.

### Form

Liquid.

### Color

Clear colorless or nearly colorless

### Odor

Alcoholic

### Odor threshold

Not available.

### pH

5.5 - 8

### Melting point/freezing point

Not available.

### Initial boiling point and boiling range

Not available.

### Flash point

116.6 °F (47.0 °C)

### Evaporation rate

Not available.

### Flammability (solid, gas)

Not applicable.

### Upper/lower flammability or explosive limits

#### Flammability limit - lower (%)

Not available.

#### Flammability limit - upper (%)

Not available.

<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	100 %
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive
<b>Oxidizing properties</b>	No oxidizing properties.
<b>Radioactivity</b>	<= 1900 MBq/ml

## 10. Stability and reactivity

<b>Reactivity</b>	Not water reactive.
<b>Chemical stability</b>	Stable at normal conditions.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.
<b>Conditions to avoid</b>	Avoid heat, sparks, open flames and other ignition sources.
<b>Incompatible materials</b>	Avoid contact with oxidizing agents. Acids.
<b>Hazardous decomposition products</b>	Decomposition of this product may emit oxides of nitrogen and carbon monoxide.

## 11. Toxicological information

### Information on toxicological effects

**Acute toxicity** Based on available data, the classification criteria are not met.

Components	Species	Test Results
Ethanol (CAS 64-17-5)		
<b>Acute</b>		
<i>Dermal</i>		
LD50	Rabbit	> 5000 mg/kg
<i>Inhalation</i>		
LC50	Rat	124.7 mg/l, 4 h
<i>Oral</i>		
LD50	Rat	7060 mg/kg

**Skin corrosion/irritation** Ethanol: Mild skin irritation  
Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation** Ethanol: Moderate eye irritation.  
Based on available data, the classification criteria are not met.

### Respiratory or skin sensitization

**Respiratory sensitization** Due to lack of data the classification is not possible.

**Skin sensitization** Due to lack of data the classification is not possible.

**Germ cell mutagenicity** Results in genetic toxicity assays (in vitro): Positive. (Florbetapir F 19)  
Results in genetic toxicity assays (in vivo): Negative (Florbetapir F 19)  
Based on available data, the classification criteria are not met.

## Carcinogenicity

Amyvid, similar to other radiopharmaceuticals contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer.

The ethanol carcinogenicity information reported below only applies when it is consumed in alcoholic beverages.

Based on available data, the classification criteria are not met.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

## Reproductive toxicity

Ethanol: Can cause adverse reproductive effects - such as birth defects, miscarriages, or infertility.

All radiopharmaceuticals, including Amyvid, have a potential to cause fetal harm. The likelihood of fetal harm depends on the stage of fetal development and the magnitude of the radiopharmaceutical dose.

Based on available data, the classification criteria are not met.

## Specific target organ toxicity - single exposure

Due to lack of data the classification is not possible.

## Specific target organ toxicity - repeated exposure

No compound-related histological findings were reported in rats and dogs administered intravenous doses for up to 28 days. (Florbetapir F 19)

Ethanol: Ingestion over a long period of time may cause kidney and liver damage. Based on available data, the classification criteria are not met.

## Aspiration hazard

No aspiration toxicity classification

## 12. Ecological information

### Ecotoxicity

Components		Species	Test Results
Ethanol (CAS 64-17-5)			
<b>Aquatic</b>			
Fish	LC50	Rainbow Trout	13 g/l, 96 hr
<i>Acute</i>			
Algae	EC50	Algae	1450 mg/l, 8 d
Crustacea	LC50	Daphnia	9.3 g/l, 48 hr

**Persistence and degradability** Not available.

**Bioaccumulative potential** Not available.

### Partition coefficient n-octanol / water (log Kow)

Ethanol -0.31

**Mobility in soil** Not available.

**Other adverse effects** Not available.

## 13. Disposal considerations

### Disposal instructions

Radioactive waste must be handled in accordance with procedures established by your Radiation Safety Officer, NRC and other applicable regulations. Dispose of waste material according to Local, State, Federal, and Provincial Environmental Regulations. Unused Amyvid and objects touching Amyvid should be considered radioactive waste. The radioactivity in Amyvid will decay quickly, but, should be considered radioactive until surveyed and documented as no longer radioactive.

## 14. Transport information

### DOT

**UN number** UN2915  
**UN proper shipping name** Radioactive material, Type A package (F-18)  
**Transport hazard class(es)**  
**Class** 7  
**Subsidiary risk** -  
**Packing group** Not applicable.  
**Special precautions for user** Not available.

**IATA**

<b>UN number</b>	UN2915
<b>UN proper shipping name</b>	Radioactive material, Type A package (F-18)
<b>Transport hazard class(es)</b>	
<b>Class</b>	7
<b>Subsidiary risk</b>	-
<b>Packing group</b>	Not applicable.
<b>Environmental hazards</b>	No.
<b>Special precautions for user</b>	Not available.
<b>Other information</b>	
<b>Passenger and cargo aircraft</b>	Allowed.
<b>Cargo aircraft only</b>	Allowed.

**IMDG**

<b>UN number</b>	UN2915
<b>UN proper shipping name</b>	Radioactive material, Type A package (F-18)
<b>Transport hazard class(es)</b>	
<b>Class</b>	7
<b>Subsidiary risk</b>	-
<b>Packing group</b>	Not applicable.
<b>Environmental hazards</b>	
<b>Marine pollutant</b>	No.
<b>EmS</b>	Not available.
<b>Special precautions for user</b>	Not available.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** This substance/mixture is not intended to be transported in bulk.

**DOT; IATA; IMDG**

**15. Regulatory information****US federal regulations****TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Ethanol (CAS 64-17-5) Listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

<b>Hazard categories</b>	Immediate Hazard - No
	Delayed Hazard - No
	Fire Hazard - Yes
	Pressure Hazard - No
	Reactivity Hazard - No

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.**US state regulations****US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

**US. Massachusetts RTK - Substance List**

Ethanol (CAS 64-17-5)

**US. New Jersey Worker and Community Right-to-Know Act**

Ethanol (CAS 64-17-5)

**US. Pennsylvania Worker and Community Right-to-Know Law**

Ethanol (CAS 64-17-5)

**US. Rhode Island RTK**

Not regulated.

**US. California Proposition 65****US - California Proposition 65 - CRT: Listed date/Carcinogenic substance**

Ethanol (CAS 64-17-5)

Listed: April 29, 2011

Listed: July 1, 1988

**US - California Proposition 65 - CRT: Listed date/Developmental toxin**

Ethanol (CAS 64-17-5)

Listed: October 1, 1987

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision****Issue date** 11-20-2014**Version #** 01**Lilly Lab Code** Health: 1  
Fire: 2  
Reactivity: 0**Disclaimer** As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.For additional information contact:  
Eli Lilly and Company  
Hazard Communication  
+1-317-651-9533