SAFETY DATA SHEET

1. Identification

Product identifier **Amyvid™**

Other means of identification

Synonyms 18F-AV-45 * Florbetapir F 18 Injection

LY Number LY3078786

Recommended use Radioactive diagnostic agent for Positron Emission Tomography (PET) imaging.

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name Eli Lilly and Company

Address Lilly Corporate Center
Indianapolis, IN 46285
United States

Telephone Phone: +1-317-276-2000

E-mail lilly_sds@lilly.com

Emergency phone number CHEMTREC: +1-800-424-9300

2. Hazard(s) identification

Physical hazards Flammable liquids Category 3

Health hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Signal word Warning

Hazard statement

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	%
Florbetapir 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.

Indication of immediate medical attention and special treatment needed

None known.

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 (CO2) 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 (COx)

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. 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. ACGIH Threshold Limit Values

Components	Type	Value
Ethanol (CAS 64-17-5)	STEL	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. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the respirator.

General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance Liquid

Physical state Liquid.

Form Aqueous Solution

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

10. Stability and reactivity

Reactivity	Not water reactive.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Avoid heat, sparks, open flames and other ignition sources.
Incompatible materials	Avoid contact with oxidizing agents. Acids.
Hazardous decomposition products	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)		
Acute		
Dermal		
LD50	Rabbit	> 5000 mg/kg
Inhalation		
LC50	Rat	124.7 mg/l, 4 h
Oral		
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): Mixed results (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.

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

IARC Monographs. Overall Evaluation of Carcinogenicity

ETHANOL IN ALCOHOLIC BEVERAGES (CAS 64-17-5) 1 Carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

ALCOHOLIC BEVERAGE CONSUMPTION (CAS 64-17-5) Known To Be Human Carcinogen

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)			
Aquatic			
Fish	LC50	Rainbow Trout	13 g/l, 96 hr
Acute			
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 (Florbetapir F-18)

Transport hazard class(es)

Class 7

Subsidiary risk -

Packing group Not available.

Special precautions for user Not available.

IATA

UN number UN2915

UN proper shipping name Radioactive material, Type A package (Florbetapir F-18)

Transport hazard class(es)

Class 7

Subsidiary risk -

Packing group Not available.

Environmental hazards No.

Special precautions for user Not available.

Other information

Passenger and cargo aircraft Allowed with restrictions.

Cargo aircraft only Allowed with restrictions.

IMDG

UN number UN2915

UN proper shipping name Radioactive material, Type A package (Florbetapir F-18)

Transport hazard class(es)

Class 7

Subsidiary risk -

Packing group Not available.

Environmental hazards

Marine pollutant No.

EmS Not available.

Special precautions for user Not available.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

DOT; IATA; IMDG

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

RCRA HAZARDOUS WASTE NO. D001 (CAS 64-17-5) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Classified hazard categories Flammable (gases, aerosols, liquids, or solids)

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.

US state regulations

California Proposition 65

California Proposition 65 - CRT: Listed date/Carcinogenic substance

ALCOHOLIC BEVERAGES, WHEN ASSOCIATED WITH ALCOHOL ABUSE (CAS 64-17-5)	Listed: April 29, 2011
	Listed: July 1, 1988

California Proposition 65 - CRT: Listed date/Developmental toxin

ETHYL ALCOHOL IN ALCOHOLIC BEVERAGES (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

Revision date 02-18-2021

Version # 04

List of abbreviations

ACGIH: American Conference of Governmental Industrial Hygienists.
AGW: Occupational threshold limit value (Arbeitsplatzgrenzwert – Germany).
DOT: Department of Transportation (49 CFR 172.101).
EC50: Effective Concentration 50%.
IARC: International Agency for Research on Cancer.
IATA: International Air Transport Association.
IBC Code: International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk.
IMDG Code: International Maritime Dangerous Goods Code.
LC50: Lethal Concentration 50%.
LD50: Lethal Dose 50%.
MARPOL: International Convention for the Prevention of Pollution from Ships.
NIOSH: National Institute for Occupational Safety & Health.
OSHA: Occupational Safety & Health Administration.
PBT: Persistent, bioaccumulative, toxic.
PEL: Permissible Exposure Limit.
STEL: Short-Term Exposure Limit.
TWA: Time Weighted Average Value.
vPvB: very Persistent, very Bioaccumulative.

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 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
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Revision information

Hazard(s) identification: Supplemental information
Composition / Information on Ingredients: Ingredients
Exposure controls/personal protection: General hygiene considerations
Physical and chemical properties: Form
Toxicological information: Mutagenicity
Regulatory information: US federal regulations
Other information, including date of preparation or last revision: Disclaimer
Other information, including date of preparation or last revision: List of abbreviations