

SAFETY DATA SHEET**SECTION 1: PRODUCT AND COMPANY IDENTIFICATION**

PRODUCT NAME: PYLARIFY (piflufolastat F18) injection

CAS Number: 1423758-00-2

Product Uses: diagnostic radiopharmaceutical

COMPANY IDENTIFICATION: Progenics Pharmaceuticals, Inc., a Lantheus company.
c/o Lantheus Holdings
331 Treble Cove Road
Billerica, MA 01862
United States of America
1-800-299-3431

EMERGENCY PHONE: **CHEMTREC 1-800-424-9300.**
For International Transportation Emergencies
Call CHEMTREC @ 1-703-527-3887.
Collect Calls are accepted

SECTION 2: HAZARDS IDENTIFICATION**EMERGENCY OVERVIEW:**

Appearance Clear liquid

Precautionary Measures PYLARIFY (piflufolastat F18) injection is a diagnostic radiopharmaceutical for intravenous use only. It emits radiation and must be handled with appropriate safety measures to minimize radiation exposure to household contacts consistent with institutional good radiation safety practices and patient management procedures.

GHS Classification This chemical is not considered hazardous by 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

GHS Label Elements None required

SECTION 3: COMPOSITION INFORMATION ON INGREDIENTS
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Active Substance	Piflufolastat F18	
CAS Number:	1423758-00-2	
Component	Concentration	CAS
F-18	NA	NA
Piflufolastat	≤ 0.01 µg/mCi at calibration time per milliliter	1423758-00-2
Ethanol	≤ 78.9 mg/mL	64-17-5
Saline	Balance	7647-14-5

SECTION 4: FIRST AID MEASURES

General Information

Eye contact	Immediately irrigate the eyes with copious amount of water for at least 15 minutes. Assure adequate flushing of the eyes by separating the eyelids with fingers. If irritation persists, seek medical attention. Notify Radiation Safety Officer immediately.
Skin contact	Immediately wash skin with copious amounts of water for at least 15 minutes while removing contaminated clothing and shoes. If irritation persists, seek medical attention. Notify Radiation Safety Officer immediately.
Inhalation	Move to fresh air. Provide oxygen or artificial respiration if needed. Notify Radiation Safety Officer immediately.
Ingestion	Never give anything by mouth to an unconscious person. Rinse mouth thoroughly. Notify Radiation Safety Officer immediately.

SECTION 5: FIRE-FIGHTING MEASURES

Flammable Properties	Material is an aqueous solution. Not expected to be flammable.
Extinguishing Media	Suitable extinguishing media: Dry chemical, Water spray, Foam
Protection of Firefighters	In the event of fire, wear self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions	Use personal protection equipment (See Section 8).
Environmental the Precautions	Prevent release to drains and waterways. Prevent release to environment.
Containment Methods	Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).
Cleanup Methods	Contain and collect spillage and place in container for disposal according to local regulations (see Section 13).

If loss or release of the radioactive contents occurs, notify your Radiation Safety Department

SECTION 7: HANDLING AND STORAGE

Handling Precautions	Avoid contact with skin and eyes.
Storage Conditions	Keep container tightly closed in a dry and well ventilated place. Store and handle in a designated area. Keep away from heat, sparks and flames.
Container Requirements	Store in sturdy containers appropriate to maintain the integrity of this material for its intended use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**Engineering Controls and Ventilation**

Use process enclosures, containment technology, or other engineering controls to keep

airborne levels below recommended exposure limit.

Respiratory Protection

Use and selection of respiratory protection is based upon engineering controls in use and potential for aerosol generation.

Eye Protection

Use equipment for eye protection tested and approved under government standards such as NIOSH (US)

Hand Protection

Impervious nitrile rubber gloves are recommended. If material is handled in solution, the solvent should also be considered when selecting protective clothing material.

Skin and Body Protection

Impervious clothing. The type of protective equipment must be selected based on the concentration and amount of dangerous substances at a specific workplace.

Hygiene

Wash hands and face before breaks and immediately after handling the product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
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Appearance

Physical State	Liquid
Color	Clear, colorless particle-free solution
Odor	Odorless

Physical and Chemical Properties

Molecular Weight	Not Available
Solubility	Soluble
Flashpoint	Not Available
Density	Not Available
pH	4.5 – 7.0
Boiling Point	> 100°C
Melting Point	< 0°C
Vapor Density	Not Available
Vapor Pressure	< 760
Radioactivity	Unit-dose of 8-10 mCi at the time of administration
Specific activity	> 1000 mCi/μmole at the time of administration
Half Life	109.8 minutes

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability	The shelf life is 10 hours post end of the synthesis stored at room temperature
Conditions to Avoid	No Data Available
Incompatible Products	Strong Oxidizing Agents
Hazardous Decomposition Products	No Data Available
Hazardous Reactions	No Data available.

SECTION 11: TOXICOLOGICAL INFORMATION

Routes of Entry	Ingestion, Inhalation, Eye Contact, Skin Contact
Acute Toxicity	May be harmful by inhalation, ingestion or skin absorption
Eye Irritation	May cause eye irritation
Skin Irritation	May causes skin irritation
Respiratory Irritation	May cause respiratory irritation
Chronic Toxicity	No information available
Carcinogenicity	No classification data on carcinogenic properties of this material is available from EPA, IARC, NTP, OSHA or ACIGIH.
Reproductive Toxicity	No effects known

SECTION 12: ECOLOGICAL INFORMATION

Environmental Toxicity:	Not available
Environmental Fate:	Not available.

SECTION 13: DISPOSAL CONSIDERATIONS**Advice on Disposal**

PYLARIFY (piflufolastat F18) injection must be considered Radioactive Waste until the activity has decayed to non-detectable levels. Radioactive waste must be handled in accordance with procedures established by your Radiation Safety Officer, NRC and other applicable regulations.

Disposal should be in accordance with applicable regional, national, and local laws and regulations. Local regulations may be more stringent than regional or national requirements.

SECTION 14: TRANSPORT INFORMATION**US DOT**

UN number: 2915 Class: 7

Proper Shipping Name: Radioactive Material, Type A Package

Marine pollutant: No Poison Inhalation Hazard: No

IATA

UN number: 2915 Class: 7

SECTION 15: REGULATORY INFORMATION

SARA 302	The following components are subject to reporting levels established by SARA Title III, Section 302: None
SARA 313	The following components are subject to reporting levels established by SARA Title III, Section 313: None
SARA 311/312	Chronic Health Hazard
California Prop 65	This material does not contain any chemical known to the State of California to cause cancer, birth defects, or any other reproductive harm.

SECTION 16: OTHER INFORMATION

MSDS preparation information

Prepared by Environment, Health and Safety 1-978-671-8673

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Other Information

The information contained in this MSDS is believed to be accurate and represents the best information reasonably available at the time of preparation. However, we make no warranty, express or implied, with respect to such information, and we assume no liability from its use.