

SAFETY DATA SHEET

Version 4.2 9/23/2025

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION	
PRODUCT NAME:	PYLARIFY (piflufolastat F18) injection
Product Uses	Diagnostic radiopharmaceutical
COMPANY IDENTIFICATION:	Progenics Pharmaceuticals, Inc., a Lantheus company 201 Burlington Road, South Building Bedford, MA 01730 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	
Classification	This material is not considered hazardous under 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)
Label Elements	None Required
Hazards not otherwise classified (HNOC)	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.

SECTION 3: COMPOSITION INFORMATION ON INGREDIENTS		
Component	Concentration	CAS
Saline	99%	7647-14-5
Ethanol	0.9%	64-17-5
Piflufolastat	<0.1%	1423758-00-2
F-18	<0.1%	NA

SECTION 4: FIRST AID MEASURES
Eye Contact

Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Obtain medical attention if symptoms occur. Notify Radiation Safety Officer immediately.

Skin Contact

Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention if symptoms occur. Notify Radiation Safety Officer immediately.

Inhalation

Move to fresh air. If breathing is difficult, give oxygen. Obtain medical attention if symptoms occur. Notify Radiation Safety Officer immediately.

Ingestion

Do not induce vomiting. Obtain medical attention if symptoms occur. Notify Radiation Safety Officer immediately.

SECTION 5: FIRE-FIGHTING MEASURES
Flammable Properties

Material is an aqueous solution. Not expected to be flammable.

Suitable Extinguishing Media

Use agent most appropriate to extinguish surrounding fire.

Protection of Firefighters

In the event of fire, wear self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES
Personal Precaution

Use personal protective equipment as required. Ensure adequate ventilation. Avoid contact with skin, eyes or clothing.

Environmental Precautions

Avoid release to the environment.

Methods for Containment and Clean Up

Soak up with inert absorbent material. Keep in suitable, closed container for disposal.

Other Information

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

SECTION 7: HANDLING AND STORAGE**Handling Precautions**

Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid contact with skin, eyes or clothing. Avoid ingestion and inhalation.

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.

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. Ensure that eye wash stations and safety showers are close to the workstation location.

Respiratory Protection

Follow the OSHA respirator regulations found in 29 CFR 1910.134. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Eye/Face Protection

Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133.

Skin and Body Protection

Wear appropriate protective gloves and clothing to prevent skin exposure.

Hygiene Measures

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES	
Physical State	Liquid
Appearance	Clear, translucent
Odor	Odorless
pH	4.5-7.0
Molecular Weight	Not Available
Solubility	Soluble
Flashpoint	Not Available
Density	Not Available
Boiling Point	Not Available
Melting Point	Not Available
Vapor Density	Not Available
Vapor Pressure	Not Available
Radioactivity	Unit-dose of 8-10 mCi at the time of administration
Specific Activity	> 1000 mCi/ μ mole at the time of administration
Half Life	109.8 minutes

SECTION 10: STABILITY AND REACTIVITY	
Stability	The shelf life is 10 hours post end of the synthesis stored at room temperature.
Conditions to Avoid	Not Available
Incompatible Products	Not Available
Hazardous Decomposition Products	None under normal use conditions
Hazardous Reactions	None under normal processing

SECTION 11: TOXICOLOGY INFORMATION	
Routes of Entry	Ingestion, Inhalation, Eye Contact, Skin Contact
Eye Irritation	May cause eye irritation
Skin Irritation	May cause skin irritation
Respiratory Irritation	May cause respiratory irritation
Sensitization	Not Available
Acute Toxicology	Not 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
Other Toxicity Information	Not available

SECTION 12: ECOLOGICAL INFORMATION

Environmental Fate	Not Available
Environmental Toxicity	Not Available

SECTION 13: DISPOSAL CONSIDERATIONS
Advice on Disposal and Packaging

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
DOT and IATA

The classification for transportation of radioactive materials will depend on the specific activity level of the material, type of isotope, as well as the quantity shipped. Specific site procedures should be followed for shipping radioactive materials or seek advice from your site Radiation Safety Officer.

SECTION 15: REGULATORY INFORMATION
United States of America

OSHA Hazard Classification	No OSHA Hazards, Radioactive– This regulation does not address hazards related to radioactivity.
SARA 302	The following components are subject to reporting levels established by SARA Title III, Section 302: None
311.312 SARA Hazard Classes	Chronic Health Hazard
313 Toxic Release Inventory Listed Chemicals/Compounds	No components listed on the SARA 313 inventory.
TSCA Inventory	Not listed. Food, drug and cosmetic products are exempt from TSCA.

SECTION 16: OTHER INFORMATION
SDS Preparation Information

Prepared by	Environment, Health and Safety 1-978-671-8673
Prepared on	9/23/2025
The information contained in this SDS 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.	