



SAFETY DATA SHEET

Version 4.2 12/1/2022

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: PYLARIFY (piflufolastat F18) injection

Product Uses diagnostic radiopharmaceutical

COMPANY IDENTIFICATION: Progenics Pharmaceuticals, Inc., a Lantheus company
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

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



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: TOXICOLOGICAL 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 Toxicity Not Available

Chronic Toxicity 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 12/1/2022

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.