

SAFETY DATA SHEET

Version 4.2 9/23/2025

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION	
PRODUCT NAME:	PYLARIFY TRUVU (piflufolastat F18) injection
Product Uses	Radioactive diagnostic drug indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer
COMPANY IDENTIFICATION:	Aphelion LLC, a Lantheus company 201 Burlington Road, South Building Bedford, MA 01730 United States of America 1-800-362-2668
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 RADIOACTIVE MATERIAL
Hazards not otherwise classified (HNOC) Handle PYLARIFY TRUVU with appropriate safety measures to minimize radiation exposure during administration. Utilize effective radiation shielding, including syringe shields, when preparing and handling PYLARIFY TRUVU. Radiopharmaceuticals, including PYLARIFY TRUVU, should be used by or under the control of healthcare providers who are qualified by specific training and experience in the safe use and handling of radionuclides, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides. Radiation exposure is associated with a dose-dependent increased risk of cancer. Ensure safe handling and preparation procedures to protect patients and health care workers from unintentional radiation exposure. Advise patients to hydrate before and after administration and to void frequently after administration.

SECTION 3: COMPOSITION INFORMATION ON INGREDIENTS		
Component	Concentration	CAS

Normal Saline	92%	7647-14-5
Ethanol	7%	64-17-5
Ascorbic Acid	0.9%	50-81-7
Piflufolastat	<0.01%	1423758-00-2

SECTION 4: FIRST AID MEASURES

Eye Contact

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

Skin Contact

Notify Radiation safety personnel immediately. Wash the affected area immediately for at least 15 minutes or until no more radioactivity can be removed

Inhalation

Notify Radiation safety personnel immediately. The amount of material should be assessed and documented. Obtain medical attention if symptoms occur.

Ingestion

Notify Radiation safety personnel immediately. Do not induce vomiting. The amount of material should be assessed and documented. Obtain medical attention if symptoms occur.

SECTION 5: FIRE-FIGHTING MEASURES

Flammable Properties

Material is an aqueous solution. Not considered 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 (such as safety goggles, lab coat, and waterproof gloves). 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 accordingly to local/national regulations.

Other Information

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

SECTION 7: HANDLING AND STORAGE

Handling Precautions

This preparation is for use by persons under license by the Nuclear Regulatory Commission or the relevant regulatory authority of an Agreement State. Use waterproof gloves. Handling time should be kept to a minimum and appropriate shielding should be used such as syringe shields and tongs. *For a complete discussion of Handling and Storage Information, please consult the full prescribing information.*

Storage Conditions

Store PYLARIFY TRUVU upright in the original container with radiation shielding at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. The expiration date and time are provided on the container label. *For a complete discussion of Handling and Storage Information, please consult the full prescribing information.*

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls and Ventilation

Properly sealed containers are not expected to require special ventilation.

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, waterproof 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, colorless to pale yellow, particulate-free
Odor	Odorless
pH	5.0-7.0
Molecular Weight	441.4
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/μmole 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 at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature].
Conditions to Avoid	Not Available
Incompatible Products	Not Available
Hazardous Decomposition Products	May emit radioactive fumes containing F-18 when heated to decomposition.
Hazardous Reactions	None under normal processing

SECTION 11: TOXICOLOGY INFORMATION

Piflufolastat F 18 has the potential to be mutagenic because of the F 18 radioisotope	
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	02Jul2026
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.	