Annora

SAFETY DATA SHEET

Section 1: Identification	
Material	Pirfenidone Tablets 267 mg & 801 mg
Recommended use	Formulated pharmaceutical active substance
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	**Camber Pharmaceuticals, Inc.**, Piscataway, NJ 08854

Section 2: Hazard(s) Identification	
Classification: GHS classification in accordance with 29 CFR 1910.1200 Acute toxicity (Oral)	Category 4
Carcinogenicity	Category 2
Hazard Statements	Harmful if swallowed Suspected of causing cancer.
Precautionary Statements	**Prevention:** Obtain special instructions before use Do not handle until all safety precautions have been read and understood. Wash skin thoroughly after handling Do not eat, drink or smoke when using this product Wear protective gloves/ protective clothing/eye protection

Section 3: Composition/Information on Ingredients	
Ingredients	Pirfenidone
CAS	53179-13-8

Section 4: First-Aid Measures	
If swallowed	Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Rinse mouth with water.
Inhalation	Move to fresh air. If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician
Skin Contact	If on skin, rinse well with water
Eye Contact	Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. If eye irritation persists, consult a specialist Keep eye wide open while rinsing.

Most important symptoms and effects, both acute and delayed	Harmful if swallowed. Suspected of causing cancer.

Section 5: Fire-Fighting Measures

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable Extinguishing Media	High volume water jet
Specific hazards during fire fighting	Do not allow run-off from firefighting to enter drains or water courses.
Hazardous combustion products	In case of fire hazardous decomposition products may be produced such as: Carbon oxides Nitrogen oxides (NOx)
Further information	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Special protective equipment for fire-fighters	Wear self-contained breathing apparatus for firefighting if necessary.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Avoid exposure Avoid dust formation. Avoid breathing dust
Environmental Precautions	Prevent product from entering drains. Prevent further leakage or spillage if safe to do so. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	Keep in suitable, closed containers for disposal

Section 7: Handling and Storage

Storage temperature	Store at 20º to 25ºC (68º to 77ºF) [see USP Controlled Room Temperature]. Keep the bottle tightly closed.

Section 8: Exposure Controls/Personal Protection

Engineering measures	No data available
Personal protective equipment	
Eye protection	Eye wash bottle with pure water Tightly fitting safety goggles
Skin and body protection	Dust impervious protective suit Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Hand protection Material **Remarks**	Protective gloves Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.
Hygiene measures	When using do not eat or drink.

	When using do not smoke. Wash hands before breaks and at the end of workday.

Section 9: Physical and Chemical Properties

Physical Form	tablet
Description	**Pirfenidone Tablets 267 mg** are white, oval, biconvex, film-coated tablets, debossed with "P 16" on one side and "H" on the other side. **Pirfenidone Tablets 801 mg** are red, oval, biconvex, film-coated tablets, debossed with "P 17" on one side and "H" on the other side. Pirfenidone film-coated tablets are supplied in bottles: NDC 31722-872-27, carton containing 3 bottles, each containing ninety 267 mg tablets (270 tablets total) with a child-resistant closure NDC 31722-873-90, carton containing 1 bottle containing ninety 801 mg tablets, with a child-resistant closure Store at 20º to 25ºC (68º to 77ºF) [see USP Controlled Room Temperature].

Section 10: Stability and Reactivity

Reactivity	No dangerous reaction known under conditions of normal use.
Chemical stability	Stable under normal conditions.
Possibility of Hazardous Reactions	No decomposition if stored and applied as directed.
Incompatible materials	No data available
Hazardous Decomposition products	No data available

Section 11: Toxicological Information

Acute toxicity Harmful if swallowed.	
Product:	
Acute oral toxicity	Acute toxicity estimate: 1,571 mg/kg Method: Calculation method
Acute inhalation toxicity	Acute toxicity estimate: 93.36 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
Acute dermal toxicity	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
Components:	
Pirfenidone: Acute oral toxicity	LD50 Oral (Rat): 1,295 mg/kg
Skin corrosion/irritation	

Not classified based on available information.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity

Components:
Pirfenidone:

Toxicity to algae/aquatic plants	ErC50 (Pseudokirchneriella subcapitata (green algae)): 67.1 mg/l Method: OECD Test Guideline 201 EbC50 (Pseudokirchneriella subcapitata (green algae)): 44 mg/l Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 18.3 mg/l Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	NOEC (Pimephales promelas (fathead minnow)): 10.6 mg/l Exposure time: 28 d Test Type: Fish early-life stage (FELS) toxicity test (OECD 210) Method: OECD Test Guideline 210 Remarks: average measured concentration
Toxicity to daphnia and other aquatic invertebrates (Chron-ic toxicity)	NOEC (Daphnia magna (Water flea)): 94 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 Remarks: average measured concentration
Toxicity to microorganisms	NOEC (activated sludge): 100 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 Remarks: Barely inhibitory on aerobic bacterial respiration (activated sludge): 578 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 Remarks: Barely inhibitory on aerobic bacterial respiration

Section 13: Disposal Considerations

Disposal methods Waste from residues	The product should not be allowed to enter drains, water courses or the soil. Do not contaminate ponds, waterways or ditches with chemical or used container. Send to a licensed waste management company. Can be disposed as waste water, when in compliance with local regulations.
Contaminated packaging	Empty remaining contents. Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers.

Section 14: Transport Information

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Domestic regulation
49 CFR
Not regulated as a dangerous good

Section 15: Regulatory Information

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

Section 16: Other Information

Issue Date : 08-10-2022

Version : 00

Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Annora Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Annora Pharma Private Limited reserves the right to revise this SDS.