

Doc. No.: SDS/FM/027

Effective Date: 30/01/18

Revision No.: 0.0

**Section 1: Chemical Product and Company Identification**

**Product Name:** Pirfenidone Tablets 267mg

**Synonyms:** --

**CAS No.:** Mixture

**Chemical Formula:** Mixture

**Molecular Weight:** Mixture

**NFPA Rating:**



Health: - ; Flammability: - ; Reactivity: - ;  
 Specific Hazard: - .

**Contact Information:**

**Corporate Address :**

Laurus Labs Limited,  
 2nd Floor, Serene Chambers, Road No #  
 7, Banjara Hills, Hyderabad – 500034  
 Ph: 040 – 3980 4333

**Section 2: Hazards Identification**

Not considered hazardous when handled under normal conditions with good house keeping.

**Section 3: Composition/ Information on Ingredients**

CAS #	Chemical name	Percent
53179-13-8	Pirfenidone	82.7
None Assigned	Mannitol (Pearlitol SD 200)	5.2
9004-34-6	Microcrystalline cellulose (Pharmacel 101)	5.6
74811-65-7	Croscarmellose sodium (AcDiSol-SD-711)	2.1
9003-39-8	Povidone (Plasdone K-29/32)	3.6
112945-52-5, 7631-86-9	Colloidal Silicon Dioxide (Aerosil 200)	0.3
4070-80-8	Sodium steryl fumarate	0.6
None Assigned	Opadry II 85F520311 Yellow	2.8

**Section 4: First Aid Measures**

**In case of inhalation:**

Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

**In case of contact with skin:**

Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

**In case of contact with eyes:**

Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice.

**In case of ingestion:**

If swallowed, wash out mouth with water, provided person is conscious. Seek medical advice.

**Section 5: Fire and Explosion Data**

**Extinguishing Media:**

Carbon dioxide, dry chemical powder or appropriate foam. Water spray.

**Special fire fighting procedures:**

Wear self-contained breathing apparatus and protective clothing to prevent contact with the skin and eyes.

**Section 6: Accidental Release Measures**

Ensuring personal safety, mark out contaminated area with signs and prevent unauthorized access. Sweep-up/absorb in suitable material, place in a container and hold for disposal. Avoid raising dust. Ventilate area and wash spill site after pick-up complete.

**Section 7: Handling and Storage**

Store at 20°C to 25°C (68-77°F) excursions permitted to between 15°C to 30°C (59-86°F)

**Section 8: Exposure Controls/ Personal Protection**
**Respiratory protection:**

Required when dusts are generated.

**Eye protection:**

Required.

**Hand protection:**

Required.

**Industrial hygiene:**

Immediately change contaminated clothing. Wash hands and face after working with substance.

**Section 9: Physical and Chemical Properties**

Physical State	:	Tablet
Color	:	Yellow
Melting Point/ Range	:	No data available
Flash Point	:	No data available
Flammability	:	No data available
Autoignition Temp	:	No data available
Oxidizing Properties	:	No data available
Explosive Properties	:	No data available
Explosion Limits	:	No data available

**Section 10: Stability and Reactivity Data**
**Conditions to be avoided**

Unknown

**Substances to be avoided**

Unknown

**Hazardous decomposition products**

Unknown

**Section 11: Toxicological Information**
**Toxicology Data**

LD50 (in Rats) : >2000mg/Kg for both oral and intraperitoneal administration.

**Section 12: Ecological Information**

Do not allow product to enter drinking water supplies, waste water or soil!

**Section 13: Disposal Considerations**

Dissolve or mix material with a suitable combustible solvent and incinerate in a chemical

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incinerator equipped with an afterburner and scrubber.  
 Material should be disposed of in keeping with all local and national legislation. Packaging should be disposed of in keeping with all local and national legislation. Handle contaminated containers as product.

**Section 14: Transport Information**
**UN number**

ADR/RID: -

IMDG: -

IATA: -

**UN proper shipping name**

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

**Transport hazard class(es)**

ADR/RID: -

IMDG: -

IATA: -

**Packaging group**

ADR/RID: -

IMDG: -

IATA: -

**Environmental hazards**

ADR/RID: no

IMDG Marine pollutant: no

IATA: no

**Special precautions for user**

no data available

**Section 15: Other Regulatory Information**

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

no data available

**Chemical Safety Assessment**

no data available

**Section 16: Other Information**
**Disclaimer:**

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.

**Revision Log:**

Revision No.	Reason for revision	Effective Date
0.0	First Issue	30/01/18

Prepared By:

  
 30/01/18

Reviewed By:

  
 30/01/18

Doc. No.: SDS/FM/026

Effective Date: 30/01/18

Revision No.: 0.0

**Section 1: Chemical Product and Company Identification**
**Product Name:** Pirfenidone Tablets 534mg

**Synonyms:** --

**CAS No.:** Mixture

**Chemical Formula:** Mixture

**Molecular Weight:** Mixture

**NFPA Rating:**

 Health: - ; Flammability: - ; Reactivity: - ;  
 Specific Hazard: - .

**Contact Information:**
**Corporate Address :**

 Laurus Labs Limited,  
 2nd Floor, Serene Chambers, Road No #  
 7, Banjara Hills, Hyderabad – 500034  
 Ph: 040 – 3980 4333

**Section 2: Hazards Identification**

Not considered hazardous when handled under normal conditions with good house keeping.

**Section 3: Composition/ Information on Ingredients**

CAS #	Chemical name	Percent
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None Assigned	Mannitol (Pearlitol SD 200)	5.2
9004-34-6	Microcrystalline cellulose (Pharmacel 101)	5.6
74811-65-7	Croscarmellose sodium (AcDiSol-SD-711)	2.1
9003-39-8	Povidone (Plasdone K-29/32)	3.6
112945-52-5, 7631-86-9	Colloidal Silicon Dioxide (Aerosil 200)	0.3
4070-80-8	Sodium steryl fumarate	0.6
None Assigned	Opadry II 85F530178 Orange	2.8

**Section 4: First Aid Measures**
**In case of inhalation:**

Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

**In case of contact with skin:**

Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

**In case of contact with eyes:**

Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice.

**In case of ingestion:**

If swallowed, wash out mouth with water, provided person is conscious. Seek medical advice.

**Section 5: Fire and Explosion Data**
**Extinguishing Media:**

Carbon dioxide, dry chemical powder or appropriate foam. Water spray.

**Special fire fighting procedures:**

Wear self-contained breathing apparatus and protective clothing to prevent contact with the skin and eyes.

**Section 6: Accidental Release Measures**

Ensuring personal safety, mark out contaminated area with signs and prevent unauthorized access. Sweep-up/absorb in suitable material, place in a container and hold for disposal. Avoid raising dust. Ventilate area and wash spill site after pick-up complete.

**Section 7: Handling and Storage**

Store at 20°C to 25°C (68-77°F) excursions permitted to between 15°C to 30°C (59-86°F)

**Section 8: Exposure Controls/ Personal Protection**
**Respiratory protection:**

Required when dusts are generated.

**Eye protection:**

Required.

**Hand protection:**

Required.

**Industrial hygiene:**

Immediately change contaminated clothing. Wash hands and face after working with substance.

**Section 9: Physical and Chemical Properties**

Physical State	:	Tablet
Color	:	Orange
Melting Point/ Range	:	No data available
Flash Point	:	No data available
Flammability	:	No data available
Autoignition Temp	:	No data available
Oxidizing Properties	:	No data available
Explosive Properties	:	No data available
Explosion Limits	:	No data available

**Section 10: Stability and Reactivity Data**
**Conditions to be avoided**

Unknown

**Substances to be avoided**

Unknown

**Hazardous decomposition products**

Unknown

**Section 11: Toxicological Information**
**Toxicology Data**

LD50 (in Rats) : >2000mg/Kg for both oral and intraperitoneal administration.

**Section 12: Ecological Information**

Do not allow product to enter drinking water supplies, waste water or soil!

**Section 13: Disposal Considerations**

Dissolve or mix material with a suitable combustible solvent and incinerate in a chemical

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incinerator equipped with an afterburner and scrubber.  
 Material should be disposed of in keeping with all local and national legislation. Packaging should be disposed of in keeping with all local and national legislation. Handle contaminated containers as product.

**Section 14: Transport Information**

**UN number**

ADR/RID: -

IMDG: -

IATA: -

**UN proper shipping name**

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

**Transport hazard class(es)**

ADR/RID: -

IMDG: -

IATA: -

**Packaging group**

ADR/RID: -

IMDG: -

IATA: -

**Environmental hazards**

ADR/RID: no

IMDG Marine pollutant: no

IATA: no

**Special precautions for user**

no data available

**Section 15: Other Regulatory Information**

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.  
**Safety, health and environmental regulations/legislation specific for the substance or mixture**

no data available

**Chemical Safety Assessment**

no data available

**Section 16: Other Information**

**Disclaimer:**

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.

**Revision Log:**

Revision No.	Reason for revision	Effective Date
0.0	First Issue	30/01/18

Prepared By:

*A*  
30/01/18

Reviewed By:

*[Signature]*  
30/01/18

# SAFETY DATA SHEET

According to Regulation (EC). No.1272/2008[CLP]

Document No.: SDS/ FM/ 0024

Version No.: 1.0

Effective Date: 08 Apr 2022

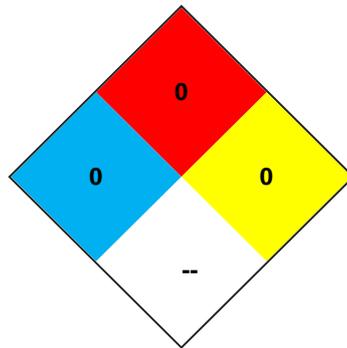
## SECTION 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

### 1.1 PRODUCT IDENTIFIERS

**Product Name** : Pirfenidone Tablets 801mg  
**Synonyms** : --  
**CAS No.** : Mixture  
**Molecular Weight** : Mixture  
**Molecular Formula** : Mixture

#### NFPA Rating

Health (Blue);  
 Flammability (Red);  
 Reactivity (Yellow);  
 Specific (White);



NFPA RATING			
Rating	NFPA-Blue	NFPA-Red	NFPA-Yellow
0	None	None	None
1	Very Low	Very Low	Very Low
2	Low	Low	Low
3	High	High	High
4	Very High	Very High	Very High
White (symbol & nature)			
OXY	- Oxidizer	W	- Use No Water
ACID	- Acid	☸	- Radiation Hazard
ALK	- Alkali	SA	- Simple Asphyxiant
COR	- Corrosive	--	- Not Applicable

### 1.2 CONTACT INFORMATION

**Corporate Office** : Laurus Labs Limited, 2nd Floor, Serene Chambers, Road No # 7, Banjara Hills, Hyderabad-500034. Telangana, India. Tel: 040-39804333  
**Registered Office** : Laurus Labs Limited, Plot No. 21, J N Pharma City, Parawada, Visakhapatnam-531021. Andhra Pradesh, India. Tel: 0891 3061222

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE:

Not a hazardous substance or mixture according to Regulation (EC) No: 1272/2008. This substance is not classified as dangerous according to Directive 67/ 548/ EEC.

### 2.2 LABEL ELEMENTS:

Not a hazardous substance or mixture according to Regulation (EC) No: 1272/2008. The product does not need to be labelled in accordance with EC directives or respective national laws.

### 2.3 OTHER HAZARDS:

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## SECTION 3: COMPOSITION/ INFORMATION ON INGREDIENTS

CAS #	Chemical name	Percent
53179-13-8	Pirfenidone	95.0 - 105.0
None assigned	Mannitol (Pearlitol SD 200)	5.2
9004-34-6	Microcrystalline cellulose (Pharmacel 101)	5.6
74811-65-7	Croscarmellose sodium (AcDiSol-SD-711)	2.1
9003-39-8	Povidone (Plasdone K-29/32)	3.6
112945-52-5, 7631-86-9	Colloidal Silicon Dioxide (Aerosil 200)	0.3

4070-80-8	Sodium steryl fumarate	0.6
None Assigned	Opadry II 85F500083 Purple	2.8

## SECTION 4: FIRST AID MEASURES

### 4.1 DESCRIPTION OF NECESSARY FIRST-AID MEASURES:

#### Eye contact:

Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention immediately.

#### Skin contact:

In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient / Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

#### Inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

#### Ingestion:

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately / Loosen tight clothing such as a collar, tie, belt or waistband.

### 4.2 MOST IMPORTANT SYMPTOMS/ EFFECTS - ACUTE AND DELAYED:

No data available.

### 4.3 INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED:

Treat symptomatically.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 EXTINGUISHING MEDIA:

**Suitable extinguishing media:** Water, Foam (Alcohol resistant AFFF), ABC Powder, Carbon Dioxide, Dry Sand, DCP (Dry Chemical Powder)

**Unsuitable extinguishing media:** For this substance/ mixture no limitations of extinguishing agents are given.

### 5.2 SPECIFIC HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE:

Carbon Oxides.

### 5.3 ADVICE FOR FIRE FIGHTERS:

Wear self contained breathing apparatus for firefighting if necessary.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 PERSONAL PRECAUTIONS PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES:

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

### 6.2 ENVIRONMENTAL PRECAUTIONS:

Ensure adequate ventilation. Use personal protective equipment. Avoid dust formation. Keep people away from and upwind of spill/leak. Evacuate personnel to safe areas.

### 6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP:

Do not flush into surface water or sanitary sewer system. Do not allow material to contaminate ground water system.

## SECTION 7: HANDLING AND STORAGE

### 7.1 PRECAUTIONS FOR SAFE HANDLING:

During handling wear personal protective equipment. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Avoid ingestion and inhalation.

### 7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES:

Store at 25°C (77°F) ; excursions permitted to 15 -30°C (59-86°F).

## SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

### 8.1 CONTROL PARAMETERS:

No Data available

### 8.2 EXPOSURE CONTROLS:

Appropriate Engineering Controls: Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and the end of workday.

### 8.3 PERSONAL PROTECTIVE EQUIPMENT :

#### Eye & Face protection:

Use personal protective equipment such as Nose mask, goggles & gloves as described by the Indian standard and/or international standard.

#### Skin & Body protection:

Long sleeved clothing. Gloves must be inspected prior to use.

#### Respiratory protection:

Required when dusts are generated.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical state &amp; Appearance</b>	: Tablet
<b>Colour</b>	: Brown Colored, Oval shaped, biconvex Film-coated tablets debossed with "LP8" on one side and plain on other side and free from physical defects.
<b>Odor</b>	: No data available
<b>Odour threshold</b>	: No data available
<b>pH</b>	: No data available
<b>Melting point/freezing point</b>	: No data available
<b>Boiling point / range</b>	: No data available
<b>Flash point</b>	: No data available
<b>Flammability (solid, gas)</b>	: No data available
<b>Flammability or explosive limits - Upper</b>	: No data available
<b>Flammability or explosive limits - Lower</b>	: No data available
<b>Evaporation rate</b>	: No data available
<b>Vapour pressure</b>	: No data available

<b>Vapour density</b>	: No data available
<b>Relative density</b>	: No data available
<b>Water solubility</b>	: No data available
<b>Partition coefficient: n-octanol/water</b>	: No data available
<b>Auto-ignition temperature</b>	: No data available
<b>Decomposition temperature</b>	: No data available
<b>Special gravity</b>	: No data available.
<b>Oxidizing properties</b>	: No data available
<b>Viscosity</b>	: Not applicable

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 REACTIVITY:

No data available.

### 10.2 CHEMICAL STABILITY:

Stable under recommended storage conditions.

### 10.3 POSSIBILITY OF HAZARDOUS REACTIONS:

No data available.

### 10.4 CONDITIONS TO AVOID:

Heat, Flames and Sparks. Extremes of temperature and direct sunlight.

### 10.5 INCOMPATIBLE MATERIALS:

No data available.

### 10.6 HAZARDOUS DECOMPOSITION PRODUCTS:

Carbon oxides.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 INFORMATION ON TOXICOLOGICAL EFFECTS:

#### Acute Toxicity:

Type	Species	Value	Unit	Any other
LD50, Oral	Rat	> 2000	mg/kg	--

#### Skin corrosion/irritation:

No data available.

#### Serious eye damage/eye irritation:

No data available.

#### Respiratory or skin sensitization:

No data available.

#### Germ cell mutagenicity:

No data available.

#### Carcinogenicity:

IARC: No component of this product presents at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

#### Reproductive toxicity:

No data available.

#### Specific target organ toxicity - single exposure:

No data available.

**Specific target organ toxicity - repeated exposure:**

No data available.

**Aspiration hazard:**

No data available.

**11.2 ADDITIONAL INFORMATION:**

The toxicological properties have not been fully investigated.

**SECTION 12: ECOLOGICAL INFORMATION**

**12.1 ECO-TOXICITY:**

Do not allow product to enter drinking water supplies, waste water or soil.

**Toxicity to algae:**

No data available.

**12.2 PERSISTENCE AND DEGRADABILITY:**

**Biodegradability:**

No data available.

**12.3 BIOACCUMULATIVE POTENTIAL:**

No data available.

**12.4 MOBILITY IN SOIL:**

No data available.

**12.5 OTHER ADVERSE EFFECTS:**

No data available.

**SECTION 13: DISPOSAL CONSIDERATIONS**

Waste Disposal methods -Waste must be segregated, stored and disposed of in accordance with central, state and local environmental control regulations.

**SECTION 14: TRANSPORT INFORMATION**

	<b>TRANSPORT</b>	<b>ADR/RID</b>	<b>IMDG</b>	<b>IATA</b>
<b>14.1 UN NUMBER</b>		--	--	--
<b>14.2 UN PROPER SHIPPING NAME</b>		Not a dangerous goods	Not a dangerous goods	Not a dangerous goods
<b>14.3 TRANSPORT HAZARD CLASS(ES)</b>		--	--	--
<b>14.4 PACKING GROUP</b>		--	--	--
<b>14.5 ENVIRONMENTAL HAZARD</b>		No	No	No
<b>14.6 SPECIAL PRECAUTIONS FOR USER</b>		--	--	--
<b>14.7 SYMBOL</b>		--	--	--

**SECTION 15: REGULATORY INFORMATION**

**Safety, health and environmental regulations specific for the substance or mixture**

This safety datasheet complies with the requirements of Regulation (EC) No. 1272/2008.

**SECTION 16: OTHER INFORMATION**

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**Revision log:**

Revision No.	Reason for Revision	Effective Date
0.0	First Issue	30 Jan 2018
1.0	Template is changed and Sections - 9 modified.	08 Apr 2022

**Prepared By:**

Shilpa. S  
(6519)

**Reviewed By:**

Bipin Kumar. S  
(6186)

**END OF SAFETY DATA SHEET**

----- This is an electronically generated SDS, and hence need not be signed -----