

ESBRIET(R) Capsules (267 mg)

SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

GHS Classification

Health Hazards:

- 3.1 Acute toxicity (Category 4)
- H302 Harmful if swallowed.

Signalword: Warning

Label:



Precautionary statements:

- P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

Other hazards

Note - no information available

SECTION 3: Composition/information on ingredients

Characterization

Pirfenidone with other inactive ingredients

Ingredients

Concentration

**GHS-Classification
(pure ingredient)**

Pirfenidone
53179-13-8

82.15 %

- Combustible dust (No category), USH003
- Acute toxicity (Category 4), H302

Croscarmellose sodium
74811-65-7

8.15 %

Microcrystalline cellulose
9004-34-6

7.39 %

For the full text of the 'Hazard statements' mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact

- rinse with tap water for 20 minutes - open eyelids forcibly

Skin contact

- when in contact with the skin, clean with soap and water

Inhalation

- in the event of symptoms get medical treatment

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4.2. Most important symptoms and effects, both acute and delayed

Note side effects - possible side effects: nausea, vomiting, dizziness, rash, dyspepsia, arthralgia, inappetence *1

4.3. Indication of any immediate medical attention and special treatment needed

Note to physician - treat symptomatically

*1 referring to: Pirfenidone

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media - adapt extinguishing media to surrounding fire conditions, water spray jet, dry powder, foam, carbon dioxide

Flash point (liquid) not applicable

5.2. Special hazards arising from the substance or mixture

Specific hazards - no particular hazards known

5.3. Advice for firefighters

Protection of fire-fighters - precipitate gases/vapours/mists with water spray

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions - no special precautions required

6.2. Environmental precautions

Environmental protection - avoid release to the environment

6.3. Methods and material for containment and cleaning up

Methods for cleaning up - take up mechanically and dispose of

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Technical measures - avoid dust formation

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Suitable materials - high density polyethylene (HDPE)

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - 15 - 30 °C

Validity - see expiry date on the label

Packaging materials - high density polyethylene (HDPE) bottles with a child-resistant polypropylene screw cap
- blister packages
- tightly closing

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (USA) air	- ACGIH-TLV: 10 mg/m ³	*2
	- OSHA-PEL: 5 mg/m ³ (respirable dust fraction)	*2
	- OSHA-PEL: 15 mg/m ³ (total dust)	*2
	- NIOSH-REL: 5 mg/m ³ (respirable dust fraction)	*2
	- NIOSH-REL: 10 mg/m ³ (total dust)	*2
	- ACGIH-TLV: 10 mg/m ³ (inhalable particulate)	*3
	- ACGIH-TLV: 3 mg/m ³ (respirable particulate)	*3
	- OSHA-PEL: 5 mg/m ³ (respirable dust)	*3
	- OSHA-PEL: 15 mg/m ³ (total dust)	*3
Threshold value (Roche) air	- IOEL (Internal Occupational Exposure Limit): 2 mg/m ³	*1
PNEC	- 1.06 mg/l, surface waters	
	- 9.4 mg/l, ground water	*1

8.2. Exposure controls

Respiratory protection - Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.
- respiratory protection not necessary during normal operations

Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)

Eye protection - safety glasses

*1 referring to: Pirfenidone
*2 referring to: Microcrystalline cellulose
*3 referring to: Croscarmellose sodium

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color white

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Form	hard gelatin capsules	
Solubility	18'200 mg/l, water (pH 3.9)	*1
	17'900 mg/l, water (pH 8.7)	*1
Partition coefficient	log P _{ow} 0.9 (octanol/water)	*1
Melting temperature	106 to 112 °C	*1

9.2. Other information

Note - no information available

*1 referring to: Pirfenidone

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Stability - stable under the conditions mentioned in chapter 7

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Note - no information available

10.5. Incompatible materials

Note - no information available

10.6. Hazardous decomposition products

Note - stable in normal conditions

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- LD ₅₀ 1'295 mg/kg (oral, rat)	*1
Local effects	no irritating effect known (skin)	*1
	no irritating effect known (eye)	*1

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Sensitization	- no information available	
Mutagenicity	- no information available	
Carcinogenicity	- no information available	
Reproductive toxicity	- no indication for teratogenicity	*1
	- no indication for adverse effects on fertility	*1
STOT-single exposure	- no information available	
STOT-repeated exposure	- no information available	
Aspiration hazard	- no information available	
Note	- possible side effects: nausea, rash, dizziness, dyspepsia, vomiting, inappetence, arthralgia	*1
Potential Health Effects	- Exposure: Ingestion	
	- Carcinogenicity: formulation not listed by NTP, IARC or OSHA	
*1 referring to:	Pirfenidone	

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	- moderately toxic for algae (<i>Pseudokirchneriella subcapitata</i>) ErC ₅₀ (72 h) 67.1 mg/l EbC ₅₀ (72 h) 44.0 mg/l NOEC (72 h) 18.3 mg/l (OECD No. 201)	*1
	- daphnid reproduction test (<i>Daphnia magna</i>) NOEC (21 d) 94 mg/l (average measured concentration) (OECD No. 211 (semi-static))	*1
	- fish early life stage test (fathead minnow) NOEC (28 d) 10.6 mg/l (average measured concentration) (OECD No. 210)	*1
	- barely inhibitory on aerobic bacterial respiration (activated sludge) NOEC (3 h) 100 mg/l EC ₂₀ (3 h) 578 mg/l (Activated Sludge Respir. Inhib. Test, OECD No. 209)	*1

12.2. Persistence and degradability

Ready biodegradability	- not readily biodegradable 9 %, 29 d (CO ₂ Evolution Test, Modified Sturm Test, OECD No. 301B)	*1
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12.3. Bioaccumulative potential

Note	- no information available	
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12.4. Mobility in soil

Note - no information available

12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Note - no information available

*1 referring to: Pirfenidone

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues

- return to supplier or hand over to authorized disposal company
- observe local/national regulations regarding waste disposal
- incinerate in qualified installation with flue gas scrubbing
- DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.

SECTION 14: Transport information

Note - not classified as Dangerous Good according to the Dangerous Goods Regulations, proper shipping name non-regulated

SECTION 15: Regulatory information

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

TSCA Status - FDA Exemption - not on inventory

Reporting Requirements

- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
- In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

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SECTION 16: Other information

Safety-lab number - BS10572
 - BS10573
 - BS10574

Full text of H-Statements referred to under section 3

H302 Harmful if swallowed.

USH003 May form combustible dust concentrations in the air

Note - Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.

Edition documentation - changes from previous version in sections 3

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.