

**ESBRIET Tablets 801 mg**Version  
1.0Revision Date:  
06/14/2025Date of last issue: -  
Date of first issue: 06/14/2025**SECTION 1. IDENTIFICATION**

Product name : ESBRIET Tablets 801 mg

Product code : RO022-0912/F12-00

Common name(s),  
synonym(s) of the substance : ESBRIET F.C. Tablets**Manufacturer or supplier's details**

Company name of supplier : Genentech, Inc.

Address : 1 DNA Way  
South San Francisco, CA 94080  
USA

Telephone : 001-(650) 225-1000

E-mail address : info.sds@roche.com

Emergency telephone

In case of emergencies: : US CHEMTREC PHONE (800)-424-9300

**Recommended use of the chemical and restrictions on use**

Recommended use : Formulated pharmaceutical active substance

**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Acute toxicity (Oral) : Category 4

Carcinogenicity : Category 1A

**GHS label elements**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.  
H350 May cause cancer.Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards**

None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Pirfenidone	53179-13-8	81.2
Cellulose	9004-34-6	6
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8	4.5
Silica	7631-86-9	2.4
Croscarmellose sodium	74811-65-7	1.8
Octadecanoic acid, magnesium salt (2:1)	557-04-0	0.5
Titanium oxide (TiO <sub>2</sub> )	13463-67-7	1
non hazardous compounds	Not Assigned	2.7

**SECTION 4. FIRST AID MEASURES**

- General advice : Move out of dangerous area.  
Show this material safety data sheet to the doctor in attendance.  
Do not leave the victim unattended.
- If inhaled : If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.
- In case of skin contact : Wash off with soap and water.
- In case of eye contact : Flush eyes with water as a precaution.  
Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
If eye irritation persists, consult a specialist.

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- If swallowed : Induce vomiting immediately and call a physician.  
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.  
Take victim immediately to hospital.
- Most important symptoms and effects, both acute and delayed : Harmful if swallowed.  
May cause cancer.
- Protection of first-aiders : First Aid responders should pay attention to self-protection and use the recommended protective clothing
- Notes to physician : Treat symptomatically.

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**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 fire fighting to enter drains or water courses.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)
- 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.

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Avoid exposure  
Use personal protective equipment.  
Avoid dust formation.  
Avoid breathing dust.  
Refer to protective measures listed in sections 7 and 8.
- Environmental precautions : Prevent product from entering drains.  
Prevent further leakage or spillage if safe to do so.

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If the product contaminates rivers and lakes or drains inform respective authorities.

Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

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**SECTION 7. HANDLING AND STORAGE**

Advice on protection against fire and explosion : Avoid dust formation.  
Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling : Avoid formation of respirable particles.  
Do not breathe vapors/dust.  
Avoid exposure - obtain special instructions before use.  
Avoid contact with skin and eyes.  
For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.  
Dispose of rinse water in accordance with local and national regulations.

Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.  
Containers which are opened must be carefully resealed and kept upright to prevent leakage.  
Electrical installations / working materials must comply with the technological safety standards.

Storage temperature : to 30 °C  
Protect against light.  
Protect from moisture.

Further information on storage stability : No decomposition if stored and applied as directed.

Packaging material : Suitable material: Stainless steel, glass

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**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Pirfenidone	53179-13-8	IOEL	2 mg/m <sup>3</sup>	Roche Industrial Hygiene Committee (RIHC)
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA	5 mg/m <sup>3</sup>	NIOSH REL

# SAFETY DATA SHEET

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		(Respirable)		
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
Silica	7631-86-9	PEL (respirable)	0.05 mg/m3	OSHA CARC
		TWA (Respirable dust)	0.05 mg/m3 (Silica)	NIOSH REL
Titanium oxide (TiO2)	13463-67-7	TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (Total dust)	10 mg/m3	OSHA P0
		TWA (Respirable particulate matter)	0.2 mg/m3 (Titanium dioxide)	ACGIH
		TWA (Respirable particulate matter)	2.5 mg/m3 (Titanium dioxide)	ACGIH
Substance name		Environmental Compartment		Value
Pirfenidone		Surface waters		1.06 mg/l

### Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

### Hand protection

In case of contact through splashing:

Material : Nitrile rubber

Break through time : > 30 min

Glove thickness : > 0.11 mm

In case of full contact:

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Material : butyl-rubber  
Break through time : > 480 min  
Glove thickness : > 0.4 mm

Remarks : Wear appropriate protective gloves to prevent skin contact.  
Replace torn or punctured gloves promptly.

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.

Hygiene measures : When using do not eat or drink.  
When using do not smoke.  
Wash hands before breaks and at the end of workday.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : tablet

Color : light yellow

Odor : Not applicable

Odor Threshold : Not applicable

pH : Not applicable

Melting point/ range : No data available

Boiling point/boiling range : No data available

Flash point : Not applicable

Evaporation rate : No data available

Self-ignition : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : Not applicable

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Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
Explosive properties	:	No data available
Oxidizing properties	:	No data available
Particle characteristics		
Particle Size Distribution	:	No data available

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**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.
Conditions to avoid	:	No data available
Incompatible materials	:	No data available
		Not applicable
Hazardous decomposition products	:	No data available
		No hazardous decomposition products are known.

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Harmful if swallowed.

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- Acute oral toxicity : Acute toxicity estimate: 1,595 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

**Cellulose:**

- Acute oral toxicity : LD50 Oral (Rat): > 5,000 mg/kg
- Acute dermal toxicity : LD50 Dermal (Rabbit): > 2,000 mg/kg

**Silica:**

- Acute oral toxicity : LD50 (Rat, male and female): > 5,000 mg/kg  
GLP: yes
- Acute inhalation toxicity : LC50 (Rat, male and female): > 5.01 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 436  
GLP: yes  
Assessment: The substance or mixture has no acute inhalation toxicity
- Acute dermal toxicity : LD50 Dermal (Rabbit): > 5,000 mg/kg  
Method: No information available.  
GLP: No information available.

**Titanium oxide (TiO<sub>2</sub>):**

- Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 425
- Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l

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Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): &gt; 5,000 mg/kg

**Skin corrosion/irritation**

Not classified due to lack of data.

**Components:****Pirfenidone:**

Result : No skin irritation

**Silica:**Species : Rabbit  
Exposure time : 4 h  
Method : OECD Test Guideline 404  
Result : No skin irritation  
GLP : No information available.**Titanium oxide (TiO<sub>2</sub>):**Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation**Serious eye damage/eye irritation**

Not classified due to lack of data.

**Components:****Pirfenidone:**

Result : No eye irritation

**Silica:**Species : Rabbit  
Result : No eye irritation  
Exposure time : 24 h  
GLP : no

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Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405

**Respiratory or skin sensitization****Skin sensitization**

Not classified due to lack of data.

**Respiratory sensitization**

Not classified due to lack of data.

**Components:****Silica:**

Test Type : Maximization Test  
Species : Guinea pig  
Assessment : Does not cause skin sensitization.  
Method : OECD Test Guideline 406  
Result : Did not cause sensitization on laboratory animals.  
GLP : yes

**Titanium oxide (TiO<sub>2</sub>):**

Species : Guinea pig  
Assessment : Does not cause skin sensitization.  
Method : OECD Test Guideline 406

**Germ cell mutagenicity**

Not classified due to lack of data.

**Components:****Pirfenidone:**

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
Metabolic activation: with and without metabolic activation  
Result: negative  
Remarks: In vitro tests did not show mutagenic effects

Test Type: Chromosome aberration test in vitro  
Metabolic activation: with and without metabolic activation  
Result: negative  
Remarks: In vitro tests did not show mutagenic effects

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: mice  
Cell type: Bone marrow  
Result: negative

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Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
Test system: Salmonella typhimurium  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative  
GLP: yes

Test Type: Microbial mutagenesis assay (Ames test)  
Test system: Escherichia coli  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative  
GLP: yes

Test Type: In vitro mammalian cell gene mutation test  
Test system: mouse lymphoma cells  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 490  
Result: negative  
GLP: yes

Genotoxicity in vivo : Species: Rat (male)  
Cell type: Bone marrow  
Application Route: Oral  
Method: OECD Test Guideline 475  
Result: negative  
GLP: no

**Carcinogenicity**

May cause cancer.

**Components:****Cellulose:**

Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**Silica:**

Species : Rat, male and female  
Application Route : Oral  
Exposure time : 2 Years  
Method : No information available.  
Result : negative  
GLP : No information available.

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Carcinogenicity - Assessment : Limited evidence of a carcinogenic effect.

<b>IARC</b>	Group 2B: Possibly carcinogenic to humans Titanium oxide (TiO <sub>2</sub> )	13463-67-7
<b>OSHA</b>	OSHA specifically regulated carcinogen Silica (crystalline silica)	7631-86-9
<b>NTP</b>	Known to be human carcinogen Silica (Silica, Crystalline (Respirable Size))	7631-86-9

**Reproductive toxicity**

Not classified due to lack of data.

**Components:****Pirfenidone:**Effects on fertility : Species: laboratory animal  
Symptoms: No effects on fertility.Effects on fetal development : Species: laboratory animal  
Result: No teratogenic potential.**Silica:**Effects on fertility : Species: Rat, male and female  
Application Route: Oral  
Dose: 100, 300, 1000 mg/kg bw/day  
General Toxicity Parent: NOAEL:  $\geq 1,000$  mg/kg body weight  
General Toxicity F1: NOAEL:  $\geq 1,000$  mg/kg body weight  
Method: OECD Test Guideline 416  
GLP: yesEffects on fetal development : Species: Mouse, female  
Application Route: Oral  
Dose: 13.4, 62.3, 289, 1340 mg/kg bw/day  
Duration of Single Treatment: 6 - 15 d  
General Toxicity Maternal: LOAEL:  $\geq 1,340$  mg/kg bw/day  
Embryo-fetal toxicity.: NOAEL:  $\geq 1,340$   $\mu$ g/kg body weight  
Method: No information available.  
GLP: No information available.**STOT-single exposure**

Not classified due to lack of data.

**STOT-repeated exposure**

Not classified due to lack of data.

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Species	: Rat, male and female
NOEL	: 4000 mg/kg
Application Route	: Oral
Exposure time	: 13 Weeks
Method	: OECD Test Guideline 408
GLP	: yes

**Aspiration toxicity**

Not classified due to lack of data.

**Experience with human exposure****Components:****Pirfenidone:**

General Information	: Symptoms: Nausea, Rash, Dizziness, digestive disorder, Vomiting, decrease in appetite, joint pain
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**Further information****Product:**

Remarks	: No data available
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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Pirfenidone:**

Toxicity to algae/aquatic plants	: ErC50 (Pseudokirchneriella subcapitata (green algae)): 67.1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201  EbC50 (Pseudokirchneriella subcapitata (green algae)): 44 mg/l Exposure time: 72 h Method: OECD Test Guideline 201  NOEC (Pseudokirchneriella subcapitata (green algae)): 18.3 mg/l Exposure time: 72 h 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

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- Toxicity to daphnia and other aquatic invertebrates (Chronic 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

**Cellulose:**
**Ecotoxicology Assessment**

- Acute aquatic toxicity : This product has no known ecotoxicological effects.
- Chronic aquatic toxicity : This product has no known ecotoxicological effects.

**Silica:**

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 5,000 mg/l  
 End point: mortality  
 Exposure time: 96 h  
 Test Type: static test  
 Analytical monitoring: no  
 Method: OECD Test Guideline 203  
 GLP: no
- Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 10,000 mg/l  
 End point: Immobilization  
 Exposure time: 24 h  
 Test Type: static test  
 Analytical monitoring: no  
 Method: OECD Test Guideline 202  
 GLP: yes
- Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 173.1 mg/l  
 End point: Growth rate  
 Exposure time: 72 h  
 Test Type: static test  
 Analytical monitoring: yes  
 Method: OECD Test Guideline 201  
 GLP: yes
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Lowest Observed Effect Concentration (Daphnia magna (Water flea)): 149.2 mg/l  
 End point: mortality

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Exposure time: 21 d  
Test Type: semi-static test  
Analytical monitoring: yes  
Method: OECD Test Guideline 211  
GLP: yes

Toxicity to microorganisms : NOEC (activated sludge): 1,000 mg/l  
End point: Respiration inhibition  
Exposure time: 3 h  
Test Type: static test  
Analytical monitoring: no  
Method: OECD Test Guideline 209  
GLP: yes

**Ecotoxicology Assessment**

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

**Titanium oxide (TiO<sub>2</sub>):**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l  
Exposure time: 96 h  
Test Type: static test

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 10,000 mg/l  
Exposure time: 96 h  
Test Type: semi-static test  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): > 1,000 mg/l  
Exposure time: 48 h  
Test Type: static test  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Test Type: static test  
Method: OECD Test Guideline 201

EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l  
Exposure time: 72 h  
Method: ISO 10253

NOEC (Skeletonema costatum (marine diatom)): 5,600 mg/l  
Exposure time: 72 h  
Method: ISO 10253

**Ecotoxicology Assessment**

Toxicity Data on Soil : Not expected to adsorb on soil.

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Other organisms relevant to : No data available  
the environment

**Persistence and degradability****Components:****Pirfenidone:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 9 %  
Exposure time: 29 d  
Method: OECD Test Guideline 301B

**Silica:**

Biodegradability : Remarks: Not applicable

**Titanium oxide (TiO<sub>2</sub>):**

Biodegradability : Remarks: Not applicable

**Bioaccumulative potential****Components:****Pirfenidone:**

Partition coefficient: n- : log Pow: 0.9  
octanol/water

**Cellulose:**

Partition coefficient: n- : Remarks: No data available  
octanol/water

**Silica:**

Partition coefficient: n- : Remarks: Not applicable  
octanol/water

**Titanium oxide (TiO<sub>2</sub>):**

Partition coefficient: n- : Remarks: No data available  
octanol/water

**Mobility in soil**

No data available

**Other adverse effects****Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82  
Protection of Stratospheric Ozone - CAA Section 602 Class I  
Substances  
Remarks: This product neither contains, nor was  
manufactured with a Class I or Class II ODS as defined by the  
U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A +  
B).

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Additional ecological information : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.  
Harmful to aquatic life.

**Components:****Pirfenidone:**

Results of PBT and vPvB assessment : Substance is not persistent, bioaccumulative, and toxic (PBT).  
Substance is not very persistent and very bioaccumulative (vPvB).

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**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.

Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Do not re-use empty containers.

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**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

**Special precautions for user**

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN,  
IMDG-Code, ICAO/IATA-DGR

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**SECTION 15. REGULATORY INFORMATION****CERCLA Reportable Quantity**

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

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**SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

Components	CAS-No.	Component TPQ (lbs)
<b>SARA 311/312 Hazards</b> : Acute toxicity (any route of exposure) Carcinogenicity		

**Clean Air Act**

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

**Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

**US State Regulations**
**Massachusetts Right To Know**

Cellulose	9004-34-6
Silica	7631-86-9
Titanium oxide (TiO <sub>2</sub> )	13463-67-7

**Pennsylvania Right To Know**

Pirfenidone	53179-13-8
Cellulose	9004-34-6
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8
Silica	7631-86-9
Titanium oxide (TiO <sub>2</sub> )	13463-67-7

**Maine Chemicals of High Concern**

Silica	7631-86-9
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**Vermont Chemicals of High Concern**
**Washington Chemicals of High Concern**
**California Prop. 65**

 WARNING: This product can expose you to chemicals including Silica, Titanium oxide (TiO<sub>2</sub>), which is/are known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

**California List of Hazardous Substances**

2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8
Silica	7631-86-9

**ESBRIET Tablets 801 mg**Version  
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Date of first issue: 06/14/2025**California Permissible Exposure Limits for Chemical Contaminants**

Cellulose	9004-34-6
Titanium oxide (TiO <sub>2</sub> )	13463-67-7

**California Regulated Carcinogens**

Silica	7631-86-9
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**The ingredients of this product are reported in the following inventories:**

AIIC	: Not in compliance with the inventory
DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL.  Pirfenidone  non hazardous compounds  Croscarmellose sodium
NZIoC	: Not in compliance with the inventory
ENCS	: Not in compliance with the inventory
ISHL	: Not in compliance with the inventory
KECI	: Not in compliance with the inventory
PICCS	: Not in compliance with the inventory
IECSC	: Not in compliance with the inventory
TCSI	: Not in compliance with the inventory
TSCA	: Product contains substance(s) not listed on TSCA inventory.
TECI	: Not in compliance with the inventory

**TSCA list**

No substances are subject to a Significant New Use Rule.

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

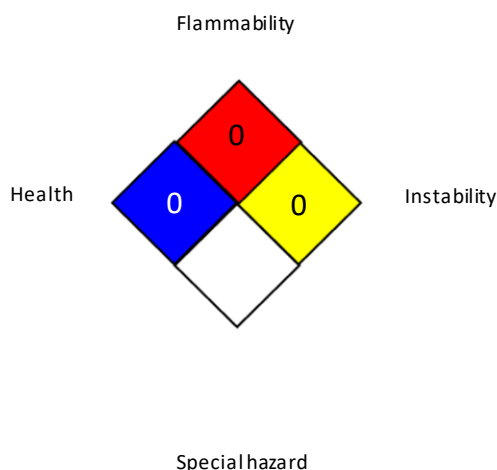
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**SECTION 16. OTHER INFORMATION****Further information**

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## NFPA 704:



## HMIS® IV:

HEALTH	*	1
FLAMMABILITY		0
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

## Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	: USA. NIOSH Recommended Exposure Limits
OSHA CARC	: OSHA Specifically Regulated Chemicals/Carcinogens
OSHA P0	: USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1	: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	: 8-hour, time-weighted average
NIOSH REL / TWA	: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA CARC / PEL	: Permissible exposure limit (PEL)
OSHA P0 / TWA	: 8-hour time weighted average
OSHA Z-1 / TWA	: 8-hour time weighted average

AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECL - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of

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Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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