

ESBRIET® F.C. Tablets (267 mg)

Version
0.0

Revision Date:
01-29-2020

Date of last issue: -
Date of first issue: 01-29-2020

SECTION 1. IDENTIFICATION

Product name : ESBRIET® F.C. Tablets (267 mg)

Product code : RO022-0912/F09

Manufacturer or supplier's details

Company name of supplier : Genentech, Inc.

Address : DNA Way 1
94080 South San Francisco
CA
USA

Telephone : 001-(650) 225-1000

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

Emergency telephone

Emergency telephone number : US Chemtrec phone (800)-424-9300

Recommended use of the chemical and restrictions on use

Recommended use : Formulated pharmaceutical active substance

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Acute toxicity (Oral) : Category 4

Carcinogenicity : Category 2

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H302 Harmful if swallowed.
H351 Suspected of causing 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/

ESBRIET® F.C. Tablets (267 mg)
Version
0.0Revision Date:
01-29-2020Date of last issue: -
Date of first issue: 01-29-2020

face protection.

Response:

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	6.0
2-Pyrrolidinone, 1-ethenyl-, homo-polymer	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 ₂)	13463-67-7	<= 1.0
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 : Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.
- In case of skin contact : If on skin, rinse well with water.
- In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.

ESBRIET® F.C. Tablets (267 mg)

Version 0.0	Revision Date: 01-29-2020	Date of last issue: - Date of first issue: 01-29-2020
----------------	------------------------------	--

If eye irritation persists, consult a specialist.

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.

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

Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

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 : 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

ESBRIET® F.C. Tablets (267 mg)

Version
0.0

Revision Date:
01-29-2020

Date of last issue: -
Date of first issue: 01-29-2020

- Advice on protection against fire and explosion : Provide appropriate exhaust ventilation at places where dust is formed.
- Advice on safe handling : Avoid formation of respirable particles.
Do not breathe vapors/dust.
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.
- Further information on storage conditions : See label, package insert or internal guidelines
- Storage temperature : to 30 °C
Protect against light.
Protect from moisture.
- Further information on storage stability : No decomposition if stored and applied as directed.

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/m3	Roche Industrial Hygiene Committee (RIHC)
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		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	TWA (Dust)	20 Million particles per cubic	OSHA Z-3

SAFETY DATA SHEET

ESBRIET® F.C. Tablets (267 mg)

Version
0.0

Revision Date:
01-29-2020

Date of last issue: -
Date of first issue: 01-29-2020

			foot (Silica)	
		TWA (Dust)	80 mg/m3 / %SiO2 (Silica)	OSHA Z-3
		TWA	6 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	10 mg/m3 (Titanium dioxide)	ACGIH
Octadecanoic acid, magnesium salt (2:1)	557-04-0	TWA (Inhalable fraction)	10 mg/m3	ACGIH
		TWA (Respirable fraction)	3 mg/m3	ACGIH

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Pirfenidone	Surface waters	1.06 mg/l

Engineering measures : No data available

Personal protective equipment

Hand protection

Material : Protective gloves

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : tablet

Color : light yellow

Odor : Not applicable

Odor Threshold : Not applicable

ESBRIET® F.C. Tablets (267 mg)

Version 0.0	Revision Date: 01-29-2020	Date of last issue: - Date of first issue: 01-29-2020
----------------	------------------------------	--

pH	:	Not applicable
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
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
Relative 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

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

ESBRIET® F.C. Tablets (267 mg)Version
0.0Revision Date:
01-29-2020Date of last issue: -
Date of first issue: 01-29-2020Hazardous decomposition : No data available
products**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Harmful if swallowed.

Product:Acute oral toxicity : Acute toxicity estimate: 1,571 mg/kg
Method: Calculation methodAcute inhalation toxicity : Acute toxicity estimate: 93.36 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation methodAcute 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 Oral (Rat): > 3,300 mg/kg

Acute dermal toxicity : LD50 Dermal (Rabbit): > 5,000 mg/kg

Titanium oxide (TiO₂):

Acute oral toxicity : LD50 (Rat): > 7,500 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 10,000 mg/kg

Octadecanoic acid, magnesium salt (2:1):

Acute oral toxicity : LD50 Oral (Rat): > 2,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

ESBRIET® F.C. Tablets (267 mg)

Version
0.0

Revision Date:
01-29-2020

Date of last issue: -
Date of first issue: 01-29-2020

Components:

Pirfenidone:

Result : No skin irritation

Silica:

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Pirfenidone:

Result : No eye irritation

Silica:

Result : No eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Silica:

Result : Did not cause sensitization on laboratory animals.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Suspected of causing 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.

IARC Group 2B: Possibly carcinogenic to humans
Titanium oxide (TiO2) 13463-67-7

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

ESBRIET® F.C. Tablets (267 mg)

Version
0.0

Revision Date:
01-29-2020

Date of last issue: -
Date of first issue: 01-29-2020

Reproductive toxicity

Not classified based on available information.

Components:

Pirfenidone:

Effects on fertility : Species: laboratory animal
Symptoms: No effects on fertility.

Effects on fetal development : Species: laboratory animal
Result: No teratogenic potential.

STOT-single exposure

Not classified based on available information.

Components:

Silica:

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

Octadecanoic acid, magnesium salt (2:1):

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure

Not classified based on available information.

Components:

Silica:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Octadecanoic acid, magnesium salt (2:1):

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration toxicity

Not classified based on available information.

Components:

Silica:

No data available

Octadecanoic acid, magnesium salt (2:1):

No data available

ESBRIET® F.C. Tablets (267 mg)Version
0.0Revision Date:
01-29-2020Date of last issue: -
Date of first issue: 01-29-2020**Experience with human exposure****Components:****Pirfenidone:**General Information : Symptoms: Nausea, Rash, Dizziness, digestive disorder,
Vomiting, decrease in appetite, joint pain

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 201EbC50 (Pseudokirchneriella subcapitata (green algae)): 44 mg/l
Method: OECD Test Guideline 201NOEC (Pseudokirchneriella subcapitata (green algae)): 18.3 mg/l
Method: OECD Test Guideline 201Toxicity 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 concentrationToxicity 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 concentrationToxicity 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

ESBRIET® F.C. Tablets (267 mg)Version
0.0Revision Date:
01-29-2020Date of last issue: -
Date of first issue: 01-29-2020**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 daphnia and other aquatic invertebrates : EC0 (Daphnia magna (Water flea)): > 10,000 mg/l
Exposure time: 24 hToxicity to algae/aquatic plants : IC50 (Pseudokirchneriella subcapitata (green algae)): 440 mg/l
Exposure time: 72 hNOEC (Pseudokirchneriella subcapitata (green algae)): 60 mg/l
Exposure time: 72 h**Ecotoxicology Assessment**

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

Other organisms relevant to the environment : No data available

Titanium oxide (TiO₂):Toxicity to fish : LC0 (Leuciscus idus (Golden orfe)): > 1,000 mg/l
Exposure time: 48 hToxicity to daphnia and other aquatic invertebrates : EC0 (Daphnia magna (Water flea)): 3 mg/l
Exposure time: 720 h**Ecotoxicology Assessment**

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

Other organisms relevant to the environment : No data available

Octadecanoic acid, magnesium salt (2:1):**Ecotoxicology Assessment**

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

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

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

Other organisms relevant to the environment : No data available

ESBRIET® F.C. Tablets (267 mg)Version
0.0Revision Date:
01-29-2020Date of last issue: -
Date of first issue: 01-29-2020**Persistence and degradability****Components:****Pirfenidone:**

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

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

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

Cellulose:

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

Silica:

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

Titanium oxide (TiO₂):

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

Octadecanoic acid, magnesium salt (2:1):

Partition coefficient: n-octanol/water : log Pow: 0.8
Method: OECD Test Guideline 107

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).

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

ESBRIET® F.C. Tablets (267 mg)

Version
0.0

Revision Date:
01-29-2020

Date of last issue: -
Date of first issue: 01-29-2020

Components:

Pirfenidone:

Results of PBT and vPvB assessment : This substance is not considered to be persistent, bioaccumulating and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulating (vPvB).

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.

ESBRIET® F.C. Tablets (267 mg)

Version
0.0

Revision Date:
01-29-2020

Date of last issue: -
Date of first issue: 01-29-2020

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

Components	CAS-No.	Component TPQ (lbs)
SARA 311/312 Hazards	: 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 SOCOMI 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

US State Regulations

Massachusetts Right To Know

Cellulose	9004-34-6
Silica	7631-86-9
Titanium oxide (TiO2)	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 (TiO2)	13463-67-7

Maine Chemicals of High Concern

Vermont Chemicals of High Concern

Washington Chemicals of High Concern

California Prop. 65

WARNING: This product can expose you to chemicals including Titanium oxide (TiO2), which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances

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

California Permissible Exposure Limits for Chemical Contaminants

Cellulose	9004-34-6
Silica	7631-86-9
Titanium oxide (TiO2)	13463-67-7

ESBRIET® F.C. Tablets (267 mg)

Version
0.0

Revision Date:
01-29-2020

Date of last issue: -
Date of first issue: 01-29-2020

The ingredients of this product are reported in the following inventories:

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Pirfenidone

non hazardous compounds

Croscarmellose sodium

AICS : Not in compliance with the inventory

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

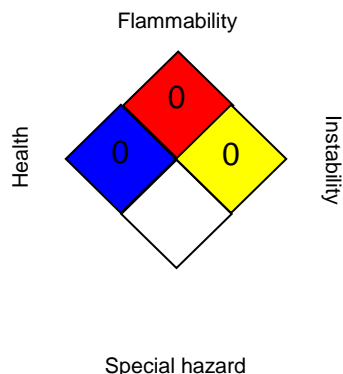
TSCA : Substance(s) not listed on TSCA inventory

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

ESBRIET® F.C. Tablets (267 mg)Version
0.0Revision Date:
01-29-2020Date of last issue: -
Date of first issue: 01-29-2020**NFPA:****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 P0	:	USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
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 P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average
OSHA Z-3 / TWA	:	8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; 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); EC_x - Concentration associated with x% response; EHS - Extremely Hazardous Substance; EL_x - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErC_x - 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; KECI - 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 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

ESBRIET® F.C. Tablets (267 mg)

Version
0.0

Revision Date:
01-29-2020

Date of last issue: -
Date of first issue: 01-29-2020

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; 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

Revision Date : 01-29-2020

The information provided in this Material 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.

US / Z8 / 1810