

# SAFETY DATA SHEET



## SIRTURO

Version 5.3	Revision Date: 2024/09/03	SDS Number: 100000010252	Date of last issue: 2023/12/15 Date of first issue: 2014/07/07
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## SECTION 1. IDENTIFICATION

Product name : SIRTURO  
Substance name : SIRTURO 100 mg tablet  
Bedaquiline Fumarate

### Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.  
Address : 1125 Trenton-Harbourton Rd  
Titusville NJ 08560  
USA  
Telephone : +16097302000  
E-mail address of person responsible for the SDS : SDSJanssen@its.jnj.com  
Emergency telephone number : CHEMTREC US: 1-800-424-9300  
CHEMTREC International: +1 703-741-5970

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

Recommended use : Finished Pharmaceutical Product  
Pharmacotherapeutic group: Antimycobacterials  
This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component.  
This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

## SECTION 2. HAZARDS IDENTIFICATION

### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

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### GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

**Prevention:** P273 Avoid release to the environment.

**Response:**

P391 Collect spillage.

**Disposal:**

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

### Other hazards

None known.

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## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Solid

### Components

Chemical name	CAS-No.	Concentration (% w/w)
BEDAQUILINE FUMARATE	845533-86-0	>= 20 - < 30
microcrystalline cellulose	9004-34-6	>= 10 - < 20
Starch	9005-84-9	>= 10 - < 20
METHYLCELLULOSE	9004-65-3	>= 1 - < 5
Octadecanoic acid, magnesium salt	557-04-0	>= 1 - < 5
Silicon, amorphous	112945-52-5	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

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## SECTION 4. FIRST AID MEASURES

If inhaled : If breathed in, move person into fresh air.  
Consult a physician.

In case of skin contact : Take off contaminated clothing and shoes immediately.  
Wash off with soap and water.  
If symptoms persist, call a physician.

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In case of eye contact : Rinse immediately with plenty of water, also under the eyelids, for at least 5 minutes.  
Remove contact lenses.  
If eye irritation persists, consult a specialist.

If swallowed : If swallowed, rinse mouth with water (only if the person is conscious).  
Call a physician immediately.

Most important symptoms and effects, both acute and delayed : Cardiac irregularities  
Diarrhoea  
Dizziness  
headache  
joint pain  
muscle pain  
nausea  
Vomiting  
Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

Notes to physician : Treat symptomatically.  
Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

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**SECTION 5. FIREFIGHTING MEASURES**

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Hazardous combustion products : No information available.

Further information : No information available.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures : In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.

Environmental precautions : Should not be released into the environment.  
Do not flush into surface water or sanitary sewer system.

Methods and materials for containment and cleaning up : Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".  
Large spills: Sweep up (intact) or vacuum with HEPA filter (broken or crushed) or via wet cleaning into suitable containers for disposal. Pick up and arrange without creating

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dust. Keep in properly labelled containers.  
Small spills: Moisten a towel, cover the spill, pick up the spill or use HEPA vacuum.

## SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : No data available

Advice on safe handling : To avoid thermal decomposition, do not overheat. Avoid inhalation, ingestion and contact with skin and eyes. Do not break, crush or spill this Finished Pharmaceutical Product. Use personal protective equipment as required.

Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight. Store in original container. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat and sources of ignition. Keep locked up.

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
BEDAQUILINE FUMARATE	845533-86-0	TWA	0.086 mg/m <sup>3</sup>	J&J OEL/PBOEL HHC
		STV	0,860 mg/100cm <sup>2</sup>	J&J OEL/PBOEL HHC
		PBOEL-HHC	2	J&J OEL/PBOEL HHC
	Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 2., Notation SKIN: has the potential for absorption via the skin.			
microcrystalline cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA	5 mg/m <sup>3</sup>	OSHA Z-1

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		(respirable fraction)		
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
Starch	9005-84-9	TWA	10 mg/m3	ACGIH
METHYLCELLULOSE	9004-65-3	TWA	10 mg/m3	ACGIH
Octadecanoic acid, magnesium salt	557-04-0	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
Silicon, amorphous	112945-52-5	TWA (Dust)	20 Million particles per cubic foot (Silica)	OSHA Z-3
		TWA (Dust)	80 mg/m3 / %SiO2 (Silica)	OSHA Z-3
		TWA	6 mg/m3 (Silica)	NIOSH REL

**Engineering measures** : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.  
If this product is processed not in accordance with the prescribed use, contact the Industrial Hygiene / Environment Health Safety Expert to assess the situation.  
Validated Industrial Hygiene Analytical methods are developed to monitor and quantify inhalable exposure to the Active Pharmaceutical Ingredient. For more information contact Bureau Veritas Laboratories - Lake Zurich (BV\_LZLab@bureauveritas.com) or the Laboratory of Occupational and Environmental Hygiene (lamh.be).

## Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection  
Remarks : Disposable gloves

Eye protection : No special precautions required.

Skin and body protection : closed work clothing

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Protective measures	: The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.
Hygiene measures	: Handle in accordance with good industrial hygiene and safety practice.

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## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: uncoated, tablet
Colour	: white
Odour	: No data available
Odour Threshold	: No data available
pH	: No data available
Melting point/ range	: No data available
Boiling point/boiling range	: No data available
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: No information available.
Self-ignition	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Density	: No data available
Solubility(ies)	
<u>Water solubility</u>	: No data available
Partition coefficient: n-octanol/water	: No data available

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Decomposition temperature	:	No data available
Viscosity		
<u>Viscosity, dynamic</u>	:	Not applicable
<u>Viscosity, kinematic</u>	:	Not applicable
Explosive properties	:	No data available
Oxidizing properties	:	No data available

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## SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	None reasonably foreseeable.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use.
Conditions to avoid	:	To avoid thermal decomposition, do not overheat. Heat, flames and sparks. Exposure to light.
Incompatible materials	:	None known.
Hazardous decomposition products	:	None known.

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## SECTION 11. TOXICOLOGICAL INFORMATION

### Acute toxicity

#### Components:

#### **BEDAQUILINE FUMARATE:**

Acute oral toxicity	:	Remarks: This information is not available.
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Remarks: No data available

#### **METHYLCELLULOSE:**

Acute oral toxicity	:	Remarks: No data available
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Remarks: No data available

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### **Silicon, amorphous:**

Acute oral toxicity : Remarks: No data available  
Acute inhalation toxicity : Remarks: No data available  
Acute dermal toxicity : Remarks: No data available  
Acute toxicity (other routes of administration) : Remarks: No data available

### **Skin corrosion/irritation**

#### **Components:**

#### **BEDAQUILINE FUMARATE:**

Remarks : No data available

#### **Starch:**

Remarks : slight irritation

#### **METHYLCELLULOSE:**

Remarks : No data available

### **Silicon, amorphous:**

Remarks : No data available

### **Serious eye damage/eye irritation**

#### **Components:**

#### **BEDAQUILINE FUMARATE:**

Remarks : No data available

#### **METHYLCELLULOSE:**

Remarks : No data available

### **Silicon, amorphous:**

Remarks : No data available

### **Respiratory or skin sensitisation**

#### **Components:**

#### **BEDAQUILINE FUMARATE:**

Remarks : No data available

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### METHYLCELLULOSE:

Remarks : No data available

### Silicon, amorphous:

Remarks : No data available

### Germ cell mutagenicity

#### Components:

### METHYLCELLULOSE:

Genotoxicity in vitro : Remarks: No data available

### Silicon, amorphous:

Genotoxicity in vitro : Remarks: No data available

### Carcinogenicity

#### Components:

### BEDAQUILINE FUMARATE:

Carcinogenicity - Assessment : Did not show carcinogenic effects in animal experiments.

### METHYLCELLULOSE:

Remarks : No data available

### Silicon, amorphous:

Remarks : No data available

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

**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 component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

#### Components:

### BEDAQUILINE FUMARATE:

Reproductive toxicity - Assessment : Animal testing did not show any effects on fertility.

Teratogenicity - Assessment : Did not show mutagenic or teratogenic effects in animal experiments.

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### METHYLCELLULOSE:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

### Silicon, amorphous:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

### STOT - single exposure

#### Components:

### BEDAQUILINE FUMARATE:

Remarks : No data available

### METHYLCELLULOSE:

Remarks : No data available

### Silicon, amorphous:

Remarks : No data available

### STOT - repeated exposure

#### Components:

### BEDAQUILINE FUMARATE:

Remarks : No data available

### METHYLCELLULOSE:

Remarks : No data available

### Silicon, amorphous:

Remarks : No data available

### Repeated dose toxicity

No data available

### Aspiration toxicity

No data available

### Experience with human exposure

No data available

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### Toxicology, Metabolism, Distribution

No data available

### Neurological effects

No data available

### Further information

#### Components:

##### Starch:

Remarks : Health injuries are not known or expected under normal use.

##### METHYLCELLULOSE:

Remarks : No data available

### Other health hazards

No data available

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## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

##### BEDAQUILINE FUMARATE:

Toxicity to algae/aquatic plants : NOECb (Scenedesmus subspicatus (fresh water algae)): >= 0.77 mg/l  
Exposure time: 72 h  
Test Type: Cell multiplication inhibition test  
Method: FDA 4.01

EbC50 (Scenedesmus subspicatus (fresh water algae)): > 0.77 mg/l  
Exposure time: 72 h  
Test Type: Cell multiplication inhibition test  
Method: FDA 4.01

NOECr (Scenedesmus subspicatus (fresh water algae)): >= 0.77 mg/l  
Exposure time: 72 h  
Test Type: Growth inhibition  
Method: FDA 4.01

ErC50 (Scenedesmus subspicatus (fresh water algae)): > 0.77 mg/l  
Exposure time: 72 h  
Test Type: Growth inhibition  
Method: FDA 4.01

ErC50 (Pseudokirchneriella subcapitata (green algae)): >

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0.00077 mg/l  
End point: Growth rate  
Exposure time: 72 h  
Test Type: Growth inhibition  
Method: OECD Test Guideline 201  
GLP: yes

EbC50 (Pseudokirchneriella subcapitata (green algae)): > 0.00077 mg/l  
End point: Growth rate  
Exposure time: 72 h  
Test Type: Growth inhibition  
Method: OECD Test Guideline 201  
GLP: yes

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.00077 mg/l  
End point: Growth rate  
Exposure time: 72 h  
Test Type: Growth inhibition  
Method: OECD Test Guideline 201  
GLP: yes

ErC50 (Anabaena flos-aquae (cyanobacterium)): > 0.00078 mg/l  
End point: Growth rate  
Exposure time: 72 h  
Test Type: Growth inhibition  
Method: OECD Test Guideline 201  
GLP: yes

EbC50 (Anabaena flos-aquae (cyanobacterium)): > 0.00078 mg/l  
End point: Growth rate  
Exposure time: 72 h  
Test Type: Growth inhibition  
Method: OECD Test Guideline 201  
GLP: yes

NOEC (Anabaena flos-aquae (cyanobacterium)): 0.00078 mg/l  
End point: Growth rate  
Exposure time: 72 h  
Test Type: Growth inhibition  
Method: OECD Test Guideline 201  
GLP: yes

M-Factor (Acute aquatic toxicity) : 1,000

Toxicity to fish (Chronic toxicity) : NOEC (Brachydanio rerio (zebrafish)): 0.0041 mg/l  
Exposure time: 35 d  
Test Type: Fish early-life stage (FELS) toxicity test (OECD

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210)  
Method: OECD Test Guideline 210  
GLP: yes

NOEC (Danio rerio (zebra fish)): 0.0041 mg/l  
Exposure time: 35 d  
Method: OECD Test Guideline 210

LOEC (Danio rerio (zebra fish)): > 0.0041 mg/l  
Exposure time: 35 d  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0047 mg/l  
Exposure time: 21 d  
Test Type: Daphnia reproduction test  
Method: OECD Test Guideline 211  
GLP: yes

LOEC (Daphnia magna (Water flea)): > 0.0047 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

NOEC (Chironomus riparius (Midge larvae)): 100 mg/kg  
Exposure time: 28 d  
Test Type: Toxicity to sediment dwelling organisms  
Method: OECD Test Guideline 218  
GLP: yes

LOEC (Midge emergence (Chironomus riparius)): > 100 mg/kg  
Exposure time: 28 d  
Method: OECD Test Guideline 218

EC50 (Midge emergence (Chironomus riparius)): > 100 mg/kg  
Exposure time: 28 d  
Method: OECD Test Guideline 218

M-Factor (Chronic aquatic toxicity) : 100

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209  
GLP: yes

NOEC (activated sludge): >= 1,000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209  
GLP: yes

EC50 (Soil microorganisms): > 100 mg/kg  
Exposure time: 28 d

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Test Type: Nitrogen transformation  
Method: OECD Test Guideline 216  
GLP: yes

NOEC (Soil microorganisms): 100 mg/kg  
Exposure time: 28 d  
Test Type: Nitrogen transformation  
Method: OECD Test Guideline 216  
GLP: yes

Toxicity to soil dwelling organisms : Test Type: Acute toxicity  
EC50 (Eisenia fetida (earthworms)): > 1,000 mg/kg  
Exposure time: 14 d  
Method: OECD Test Guideline 207  
GLP: yes

Test Type: Acute toxicity  
NOEC (Eisenia fetida (earthworms)): 1,000 mg/kg  
Exposure time: 14 d  
Method: OECD Test Guideline 207  
GLP: yes

Test Type: Reproduction Test  
EC50 (Springtail (Collembola)): > 1,000 mg/kg  
Exposure time: 28 d  
Method: ISO 11267  
GLP: yes

Test Type: Reproduction Test  
NOEC (Springtail (Collembola)): 250 mg/kg  
Exposure time: 28 d  
Method: ISO 11267  
GLP: yes

LOEC (Springtail (Collembola)): 500 mg/kg  
Exposure time: 28 d  
Method: ISO 11267

Plant toxicity : NOEC: 1,000 mg/kg  
Exposure time: 16 d  
Species: Terrestrial plants  
Method: OECD Test Guideline 208  
GLP: yes

EC50: > 1,000 mg/kg  
Exposure time: 16 d  
Species: Terrestrial plants  
Method: OECD Test Guideline 208  
GLP: yes

## METHYLCELLULOSE:

Toxicity to fish : Remarks: No data available

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**Silicon, amorphous:**

Toxicity to fish : (Brachydanio rerio (zebrafish)): > 10,000 mg/l  
Exposure time: 96 h  
Test Type: LC50

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae/aquatic plants : Remarks: No data available

**Persistence and degradability****Components:****BEDAQUILINE FUMARATE:**

Biodegradability : aerobic  
Inoculum: activated sludge  
Result: Not readily biodegradable.  
Exposure time: 28 d  
Method: OECD Test Guideline 301F  
GLP: yes

Stability in water : Test Type: anaerobic  
Degradation half life (DT50): 134 d  
Method: OECD Test Guideline 308  
GLP: yes  
Remarks: sediment 1

Test Type: anaerobic  
Degradation half life (DT50): 5.3 d  
Method: OECD Test Guideline 308  
GLP: yes  
Remarks: Fresh water 1

Test Type: aerobic  
Degradation half life (DT50): 163 d  
Method: OECD Test Guideline 308  
GLP: yes  
Remarks: total system 2

Test Type: aerobic  
Degradation half life (DT50): 257 d  
Method: OECD Test Guideline 308  
GLP: yes  
Remarks: total system 1

Test Type: aerobic  
Degradation half life (DT50): 2.3 d  
Method: OECD Test Guideline 308  
GLP: yes  
Remarks: Fresh water 2

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Test Type: aerobic  
Degradation half life (DT50): 2.7 d  
Method: OECD Test Guideline 308  
GLP: yes  
Remarks: Fresh water 1

### METHYLCELLULOSE:

Biodegradability : Remarks: No data available

### Silicon, amorphous:

Biodegradability : Remarks: No data available

### Bioaccumulative potential

#### Components:

### BEDAQUILINE FUMARATE:

Bioaccumulation : Species: Oncorhynchus mykiss (rainbow trout)  
Bioconcentration factor (BCF): 1,433  
Exposure time: 28 d  
Method: OECD Test Guideline 305  
GLP: yes

Species: Oncorhynchus mykiss (rainbow trout)  
Bioconcentration factor (BCF): 2,049  
Exposure time: 28 d  
Method: OECD Test Guideline 305  
GLP: yes

Partition coefficient: n-octanol/water : log Pow: 2.93  
Method: OECD Test Guideline 117  
GLP: yes

### METHYLCELLULOSE:

Bioaccumulation : Remarks: No data available

### Octadecanoic acid, magnesium salt:

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

### Silicon, amorphous:

Bioaccumulation : Remarks: No data available

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

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**Mobility in soil****Components:****BEDAQUILINE FUMARATE:**

Distribution among environmental compartments	: Adsorption/Soil Koc: 40428 - 370745 Method: OECD Test Guideline 106
Stability in soil	: Test Type: Aerobic transformation in soil Dissipation time: 344 d Method: OECD Test Guideline 307 GLP: yes Remarks: soil 3
	: Test Type: Aerobic transformation in soil Dissipation time: > 365 d Method: OECD Test Guideline 307 GLP: yes Remarks: soil 2
	: Test Type: Aerobic transformation in soil Dissipation time: > 365 d Method: OECD Test Guideline 307 GLP: yes Remarks: soil 1

**METHYLCELLULOSE:**

Distribution among environmental compartments	: Remarks: No data available
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**Other adverse effects****Components:****BEDAQUILINE FUMARATE:**

Results of PBT and vPvB assessment	: PBT substance
Additional ecological information	: No data available

**METHYLCELLULOSE:**

Results of PBT and vPvB assessment	: No information available.
Additional ecological information	: No data available

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : In accordance with National, Federal, State and Local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(BEDAQUILINE FUMARATE)

Class : 9

Packing group : III

Labels : 9

**IATA-DGR**

UN/ID No. : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(BEDAQUILINE FUMARATE)

Class : 9

Packing group : III

Labels : 9

Packing instruction (cargo aircraft) : 956

Packing instruction (LQ) : Y956

Packing instruction (EQ) : E1

Packing instruction (passenger aircraft) : 956

Packing instruction (LQ) : Y956

Remarks : Special Provision A197: Environmentally hazardous substances, classified under UN 3077 or UN 3082, when transported in single or combination packagings containing a net quantity per single or inner packaging of 5 L or less for liquids or having a net mass of 5 kg or less for solids, are not subject to any other provisions of the IATA DGR provided the packagings meet the general provisions of IATA DGR 5.0.2.4.1, 5.0.2.6.1.1 and 5.0.2.8.. This substance can be shipped under 'de minimis' quantities' provisions if the net quantity per inner package <= 1mL for liquids or <= 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of IATA DGR §2.6.10 are met.

**IMDG-Code**

UN number : UN 3077

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Proper shipping name	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (BEDAQUILINE FUMARATE)
Class	: 9
Packing group	: III
Labels	: 9
EmS Code	: F-A, S-F
Marine pollutant	: yes
Remarks	: 2.10.2.7: Environmentally Hazardous Substances/Marine Pollutants, classified under UN 3077 or UN 3082, packaged in single or combination packagings containing a net quantity per single of inner packaging of 5L or less for liquids or having a net mass per single of inner packaging of 5kg or less for solids are not subject to the IMDG provided the packagings meet the general requirements of 4.1.1.1, 4.1.1.2, and 4.1.1.4 to 4.1.1.8., This substance can be shipped under 'de minimi's quantities' provisions if the net quantity per inner package <= 1mL for liquids or <= 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of ADR/RID/ADN/IMDG §3.5.1.4 are met.

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

Not applicable for product as supplied.

### National Regulations

#### 49 CFR

UN/ID/NA number	: UN 3077
Proper shipping name	: Environmentally hazardous substance, solid, n.o.s. (BEDAQUILINE FUMARATE)
Class	: 9
Packing group	: III
Labels	: 9
ERG Code	: 171
Marine pollutant	: yes
Remarks	: 49 CFR 171.4 - Marine Pollutant Exception: Except when transporting aboard a vessel, the requirements of this subchapter do not apply to non-bulk packagings transported by motor vehicles, rail cars, and aircraft., This substance can be shipped under 'de minimi's quantities' provisions if the net quantity per inner package <= 1mL for liquids or <= 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of 49 CFR 173.4b are met.

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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## SECTION 15. REGULATORY INFORMATION

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### US State Regulations

#### Massachusetts Right To Know

microcrystalline cellulose	9004-34-6
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#### Pennsylvania Right To Know

alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1)	5989-81-1
BEDAQUILINE FUMARATE	845533-86-0
microcrystalline cellulose	9004-34-6
Starch	9005-84-9
AC-DI-SOL	Not Assigned

#### Maine Chemicals of High Concern

Product does not contain any listed chemicals

#### Vermont Chemicals of High Concern

Product does not contain any listed chemicals

#### Washington Chemicals of High Concern

Product does not contain any listed chemicals

#### California Permissible Exposure Limits for Chemical Contaminants

microcrystalline cellulose	9004-34-6
Octadecanoic acid, magnesium salt	557-04-0

### Other regulations

Restricted to professional users.

This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

ACGIH	: US. ACGIH Threshold Limit Values
ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
J&J OEL/PBOEL HHC	: J&J OEL/PBOEL HHC
NIOSH REL	: USA. NIOSH Recommended Exposure Limits

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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
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA	:	Time weighted average
ACGIH / TWA	:	8-hour, time-weighted average
J&J OEL/PBOEL HHC / STV	:	STV: Surface Target Value
J&J OEL/PBOEL HHC / TWA	:	Time weighted average
J&J OEL/PBOEL HHC / PBOEL-HHC	:	PBOEL-HHC
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

AIIC - 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 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; TECI - 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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### Date and Number Formats

This document uses the following notation for printing dates and numbers:

**Date:** Dec 31th, 2012 as 2012/12/31

**Numbers:** 123456,78 as 123,456.78

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