

SAFETY DATA SHEET



Version 4.5	Revision Date: 2024/09/05	SDS Number: 100000012931	Date of last issue: 2023/12/15 Date of first issue: 2019/11/05
----------------	------------------------------	-----------------------------	---

SECTION 1. IDENTIFICATION

Substance name : SIRTURO 20mg tablet
Bedaquiline Fumarate
Sirturo Ped

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

SAFETY DATA SHEET



Version 4.5	Revision Date: 2024/09/05	SDS Number: 100000012931	Date of last issue: 2023/12/15 Date of first issue: 2019/11/05
----------------	------------------------------	-----------------------------	---

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture

:

Mixture

Chemical nature

:

Solid

Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	$\geq 70 - < 90$
BEDAQUILINE FUMARATE	845533-86-0	$\geq 10 - < 20$
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3	$\geq 1 - < 5$
Silicon, amorphous	112945-52-5	$\geq 1 - < 5$
COLLOIDAL ANHYDROUS SILICA	112945-52-5	$\geq 1 - < 5$

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

If inhaled

:

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

SAFETY DATA SHEET



Version 4.5	Revision Date: 2024/09/05	SDS Number: 100000012931	Date of last issue: 2023/12/15 Date of first issue: 2019/11/05
----------------	------------------------------	-----------------------------	---

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	:	No information available.
Notes to physician	:	Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Hazardous combustion products	:	Carbon oxides Sodium oxides
Further information	:	No information available.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus.

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. Evacuate personnel to safe areas. For disposal considerations see section 13.
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	:	Small spills: Moisten a towel, cover the spill, pick up the spill or use HEPA vacuum. 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 dust. Keep in properly labelled containers. Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".

SECTION 7. HANDLING AND STORAGE

SAFETY DATA SHEET



Version 4.5	Revision Date: 2024/09/05	SDS Number: 100000012931	Date of last issue: 2023/12/15 Date of first issue: 2019/11/05
----------------	------------------------------	-----------------------------	---

- Advice on protection against fire and explosion : No data available
- Advice on safe handling : Do not break, crush or spill this Finished Pharmaceutical Product.
To avoid thermal decomposition, do not overheat.
For personal protection see section 8.
Avoid inhalation, ingestion and contact with skin and eyes.
- 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.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0
BEDAQUILINE FUMARATE	845533-86-0	TWA	0.086 mg/m ³	J&J OEL/PBOEL HHC
		STV	0,860 mg/100cm ²	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.			
HYDROXYPROPYLMETHYLC	9004-65-3	TWA	10 mg/m ³	ACGIH

SAFETY DATA SHEET



Version 4.5	Revision Date: 2024/09/05	SDS Number: 100000012931	Date of last issue: 2023/12/15 Date of first issue: 2019/11/05
----------------	------------------------------	-----------------------------	---

ELLULOSE (HPMC)				
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
COLLOIDAL ANHYDROUS SILICA	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

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.

SAFETY DATA SHEET



Version 4.5	Revision Date: 2024/09/05	SDS Number: 100000012931	Date of last issue: 2023/12/15 Date of first issue: 2019/11/05
----------------	------------------------------	-----------------------------	---

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: tablet
Colour	: white, to, off-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
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Density	: No data available

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.
Incompatible materials	: None known.
Hazardous decomposition products	: None known.

Version 4.5	Revision Date: 2024/09/05	SDS Number: 100000012931	Date of last issue: 2023/12/15 Date of first issue: 2019/11/05
----------------	------------------------------	-----------------------------	---

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity****Components:****Cellulose:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

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

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

COLLOIDAL ANHYDROUS SILICA:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

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

Skin corrosion/irritation**Components:****Cellulose:**

Species : Rabbit
Remarks : No skin irritation

BEDAQUILINE FUMARATE:

Remarks : No data available

Silicon, amorphous:

Remarks : No data available

COLLOIDAL ANHYDROUS SILICA:

Species : Rabbit
Result : No skin irritation

SAFETY DATA SHEET



Version 4.5	Revision Date: 2024/09/05	SDS Number: 100000012931	Date of last issue: 2023/12/15 Date of first issue: 2019/11/05
----------------	------------------------------	-----------------------------	---

Serious eye damage/eye irritation

Components:

Cellulose:

Species : Rabbit
Remarks : No eye irritation

BEDAQUILINE FUMARATE:

Remarks : No data available

Silicon, amorphous:

Remarks : No data available

COLLOIDAL ANHYDROUS SILICA:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitisation

Components:

Cellulose:

Species : Guinea pig
Remarks : Did not cause sensitisation on laboratory animals.

BEDAQUILINE FUMARATE:

Remarks : No data available

Silicon, amorphous:

Remarks : No data available

Germ cell mutagenicity

Components:

Silicon, amorphous:

Genotoxicity in vitro : Remarks: No data available

Carcinogenicity

Components:

BEDAQUILINE FUMARATE:

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

SAFETY DATA SHEET



Version 4.5	Revision Date: 2024/09/05	SDS Number: 100000012931	Date of last issue: 2023/12/15 Date of first issue: 2019/11/05
----------------	------------------------------	-----------------------------	---

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.

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

Silicon, amorphous:

Remarks : No data available

STOT - repeated exposure

Components:

BEDAQUILINE FUMARATE:

Remarks : No data available

Silicon, amorphous:

Remarks : No data available

SAFETY DATA SHEET



Version 4.5	Revision Date: 2024/09/05	SDS Number: 100000012931	Date of last issue: 2023/12/15 Date of first issue: 2019/11/05
----------------	------------------------------	-----------------------------	---

Repeated dose toxicity

No data available

Aspiration toxicity

No data available

Experience with human exposure

No data available

Toxicology, Metabolism, Distribution

No data available

Neurological effects

No data available

Further information

No data available

Other health hazards

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:

Toxicity to fish : Remarks: No data available

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

SAFETY DATA SHEET



Version	Revision Date:	SDS Number:	Date of last issue: 2023/12/15
4.5	2024/09/05	100000012931	Date of first issue: 2019/11/05

Test Type: Growth inhibition
Method: FDA 4.01

ErC50 (*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

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

SAFETY DATA SHEET



Version 4.5	Revision Date: 2024/09/05	SDS Number: 100000012931	Date of last issue: 2023/12/15 Date of first issue: 2019/11/05
----------------	------------------------------	-----------------------------	---

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 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 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

SAFETY DATA SHEET



Version 4.5	Revision Date: 2024/09/05	SDS Number: 100000012931	Date of last issue: 2023/12/15 Date of first issue: 2019/11/05
----------------	------------------------------	-----------------------------	---

GLP: yes

EC50 (Soil microorganisms): > 100 mg/kg

Exposure time: 28 d

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

Version 4.5	Revision Date: 2024/09/05	SDS Number: 100000012931	Date of last issue: 2023/12/15 Date of first issue: 2019/11/05
----------------	------------------------------	-----------------------------	---

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Toxicity to fish : Remarks: No data available

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

COLLOIDAL ANHYDROUS SILICA:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10,000 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
Exposure time: 24 h

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

SAFETY DATA SHEET



Version 4.5	Revision Date: 2024/09/05	SDS Number: 100000012931	Date of last issue: 2023/12/15 Date of first issue: 2019/11/05
----------------	------------------------------	-----------------------------	---

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

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

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Biodegradability : Remarks: No data available

Silicon, amorphous:

Biodegradability : Remarks: No data available

COLLOIDAL ANHYDROUS SILICA:

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

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

SAFETY DATA SHEET



Version 4.5	Revision Date: 2024/09/05	SDS Number: 100000012931	Date of last issue: 2023/12/15 Date of first issue: 2019/11/05
----------------	------------------------------	-----------------------------	---

Bioaccumulation : Remarks: No data available

Silicon, amorphous:

Bioaccumulation : Remarks: No data available

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

COLLOIDAL ANHYDROUS SILICA:

Bioaccumulation : Remarks: No data available

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

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

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Distribution among environmental compartments : Remarks: No data available

COLLOIDAL ANHYDROUS SILICA:

Distribution among environmental compartments : Remarks: No data available

SAFETY DATA SHEET



Version 4.5	Revision Date: 2024/09/05	SDS Number: 100000012931	Date of last issue: 2023/12/15 Date of first issue: 2019/11/05
----------------	------------------------------	-----------------------------	---

Other adverse effects

Components:

BEDAQUILINE FUMARATE:

Results of PBT and vPvB assessment : PBT substance

Additional ecological information : No data available

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

COLLOIDAL ANHYDROUS SILICA:

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

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

SAFETY DATA SHEET



Version 4.5	Revision Date: 2024/09/05	SDS Number: 100000012931	Date of last issue: 2023/12/15 Date of first issue: 2019/11/05
----------------	------------------------------	-----------------------------	---

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 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 IATA DGR §2.6.10 are met.

IMDG-Code

UN number : UN 3077

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

SAFETY DATA SHEET



Version	Revision Date:	SDS Number:	Date of last issue: 2023/12/15
4.5	2024/09/05	100000012931	Date of first issue: 2019/11/05

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.

SECTION 15. REGULATORY INFORMATION

US State Regulations

Massachusetts Right To Know

Cellulose	9004-34-6
-----------	-----------

Pennsylvania Right To Know

Cellulose	9004-34-6
BEDAQUILINE FUMARATE	845533-86-0
CROSPVIDONE	9003-39-8
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3

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 List of Hazardous Substances

CROSPVIDONE	9003-39-8
-------------	-----------

California Permissible Exposure Limits for Chemical Contaminants

Cellulose	9004-34-6
Silicon, amorphous	112945-52-5

SAFETY DATA SHEET



Version 4.5	Revision Date: 2024/09/05	SDS Number: 100000012931	Date of last issue: 2023/12/15 Date of first issue: 2019/11/05
----------------	------------------------------	-----------------------------	---

COLLOIDAL ANHYDROUS SILICA

112945-52-5

Other regulations

Restricted to professional users.

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

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

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
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 -

SAFETY DATA SHEET



Version 4.5	Revision Date: 2024/09/05	SDS Number: 100000012931	Date of last issue: 2023/12/15 Date of first issue: 2019/11/05
----------------	------------------------------	-----------------------------	---

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 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

Revision Date : 2024/09/05

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

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.

US / EN