according to Regulation (EC) No. 1907/2006



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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name

: BEDAQUILINE FUMARATE

Substance name

: BEDAQUILINE FUMARATE

3-Quinolineethanol, 6-bromo-alpha-[2-(dimethylamino)ethyl]-

2-methoxy-alpha-1-naphthalenyl-beta-phenyl-, (alphaS,betaR)-, (2E)-2-butenedioate (1:1) (salt)

CAS-No.

: 845533-86-0

Reference number

: JNJ-16175328-AEP

R403323

Product code

116620

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-

: Active Pharmaceutical Ingredient

stance/Mixture

1.3 Details of the supplier of the safety data sheet

Company

: Janssen Pharmaceutica NV

Turnhoutseweg 30 2340 Beerse Belgium

Telephone

: +3214602111

Telefax

: +3214602841

E-mail address

Responsible/issuing person

: SDSJanssen@its.jnj.com

1.4 Emergency telephone number

CHEMTREC BE: +(32)-28083237

CHEMTREC International: +1 703-527-3887

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Short-term (acute) aquatic hazard, Cate-

H400: Very toxic to aquatic life.

gory 1

egory 1

Long-term (chronic) aquatic hazard, Cat-

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

according to Regulation (EC) No. 1907/2006



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2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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 ap-

proved waste disposal plant.

2.3 Other hazards

PBT substance

Warning! May form combustible dust concentrations in air.

SECTION 3: Composition/information on ingredients

3.1 Substances

Substance name

: BEDAQUILINE FUMARATE

Chemical nature

: Solid

Hazardous components

Chemical name	CAS-No. EC-No.	Concentration (%)	
WEL substance :			
BEDAQUILINE 845533-86-0 FUMARATE		<= 100	

SECTION 4: First aid measures

4.1 Description of first aid measures

If inhaled

: If breathed in, move person into fresh air.

If symptoms persist, call a physician.

In case of skin contact

: Take off contaminated clothing and shoes immediately.

Wash off with soap and water.

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If symptoms persist, call a physician.

In case of eye contact

: Remove contact lenses.

Rinse immediately with plenty of water, also under the eyelids,

for at least 5 minutes.

If eye irritation persists, consult a specialist.

If swallowed

: If swallowed, rinse mouth with water (only if the person is con-

scious).

Call a physician immediately.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms

: headache

Dizziness

Cardiac irregularities

nausea Vomiting Diarrhoea muscle pain joint pain

4.3 Indication of any immediate medical attention and special treatment needed

Treatment

: Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water mist

Dry powder

Foam

Carbon dioxide (CO2)

Aqueous film forming foam (AFFF).

Unsuitable extinguishing

media

: Water spray jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

Combustible material

fighting

Heating can release hazardous gases.

Risk of dust explosion.

Hazardous combustion prod-

: No hazardous combustion products are known

ucts

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5.3 Advice for firefighters

Special protective equipment

for firefighters

: In the event of fire, wear self-contained breathing apparatus. Firefighters must wear fire resistant personal protective

equipment.

Further information

: In the event of fire, cool tanks with water spray.

Avoid dust formation.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions

: Evacuate personnel to safe areas.

Avoid dust formation. Avoid breathing dust.

Keep away from open flames, hot surfaces and sources of

ignition.

6.2 Environmental precautions

Environmental precautions

: Do not flush into surface water or sanitary sewer system.

Should not be released into the environment.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up

: Keep in properly labelled containers.

Pick up and arrange disposal without creating dust. Sweep up and shovel into suitable containers for disposal.

Keep in suitable, closed containers for disposal.

Treat recovered material as described in the section "Disposal

considerations".

6.4 Reference to other sections

For disposal information, see section 13, Refer to protective measures listed in sections 7 and 8.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

: Ensure all equipment is electrically grounded before beginning

transfer operations.

To avoid thermal decomposition, do not overheat. Keep away from heat and sources of ignition.

Avoid formation of dust and aerosols.

Use personal protective equipment as required.

Advice on protection against

fire and explosion

: Avoid dust formation. Keep away from heat and sources of

ignition.

Hygiene measures : Hand

: Handle in accordance with good industrial hygiene and safety

according to Regulation (EC) No. 1907/2006



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practice.

Dust explosion class

: St2

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

: 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.

Recommended storage tem-

perature

: 15 - 25 °C

7.3 Specific end use(s)

Specific use(s)

: Consult the technical guidelines for the use of this sub-

stance/mixture.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis	
BEDAQUILINE FUMARATE	845533-86- 0	PBOEL-HHC	1 B	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 1B.				
		TWA	0,290 mg/m3	J&J OEL/PBOEL HHC	

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Fresh water

Value: 0,000077 mg/l

8.2 Exposure controls

Engineering measures

Engineering controls should be used as the primary means to control possible exposures. Use process enclosures, local exhaust ventilation or other engineering controls to keep exposure levels below recommended exposure limits.

Personal protective equipment

Eye protection

: Safety glasses with side-shields

Hand protection

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Remarks

: Impervious gloves Nitrile rubber Neoprene gloves Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact).

Skin and body protection

: closed work clothing Long sleeved clothing

Respiratory protection

: Wear a self-contained breathing apparatus in all circumstances when the mask and cartridge do not give adequate protection (e.g. : medium confinement/insufficient oxygen/in case of large uncontrolled emissions).

Use only respiratory protection that conforms to international/

national standards.

Respirator with a particle filter (EN 143)

P2

Engineering controls should always be the primary method of

controlling exposures.

If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances pre-

sent.

Protective measures

The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

: powder

Colour

: white

Odour

: No data available

Odour Threshold

: No data available

pΗ

: 5 - 6, Concentration: 10 g/l (20 °C)

Melting point/range

: 180 - 195 °C

Boiling point/boiling range

: No data available

Flash point

: No data available

Evaporation rate

: No data available

according to Regulation (EC) No. 1907/2006



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Flammability (solid, gas)

: No information available.

Burning number

: 2, 20 °C, Air

2, 100 °C, Air

Upper explosion limit

: No data available

Lower explosion limit

: 60 g/m3

Vapour pressure

: No data available

Relative vapour density

: No data available

Relative density

: No data available

Density

: No data available

Solubility(ies)

Water solubility

: 0,03 g/l

Partition coefficient: n-

octanol/water

log Pow: 2,93

Method: OECD Test Guideline 117

GLP: yes

Auto-ignition temperature

: 400 °C

Method: M.I.T. Dust Cloud BAM METHOD

Decomposition temperature

: 210 °C

Minimum T

Viscosity

Viscosity, dynamic

: No data available

Viscosity, kinematic

: No data available

Explosive properties

: No data available

Oxidizing properties

: No data available

9.2 Other information

Impact sensitivity

: Not impact sensitive.

39 J

Molecular weight

: 671,59 g/mol

Self-ignition

No data available

according to Regulation (EC) No. 1907/2006



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SECTION 10: Stability and reactivity

10.1 Reactivity

None reasonably foreseeable.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions

: Risk of dust explosion.

No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Conditions to avoid

Heat, flames and sparks.

To avoid thermal decomposition, do not overheat.

10.5 Incompatible materials

Materials to avoid

: Strong oxidizing agents

10.6 Hazardous decomposition products

Carbon oxides, HBr, Nitrogen oxides (NOx)

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product:

Acute oral toxicity

: Remarks: No data available

Acute inhalation toxicity

: Remarks: No data available

Acute dermal toxicity

: Remarks: No data available

Skin corrosion/irritation

Product:

Remarks: No data available

Serious eye damage/eye irritation

Product:

Remarks: No data available

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Respiratory or skin sensitisation

Product:

Remarks: No data available

Germ cell mutagenicity

No data available

Carcinogenicity

Product:

Carcinogenicity - Assess-

ment

: Did not show carcinogenic effects in animal experiments.

Reproductive toxicity

Product:

Reproductive toxicity -

Assessment

: Animal testing did not show any effects on fertility.

Teratogenicity - Assessment

Did not show mutagenic or teratogenic effects in animal

experiments.

STOT - single exposure

Product:

Remarks: No data available

STOT - repeated exposure

Product:

Remarks: No data available

Repeated dose toxicity

No data available

Aspiration toxicity

No data available

SECTION 12: Ecological information

12.1 Toxicity

Product:

Toxicity to algae

NOECb (Scenedesmus subspicatus (fresh water algae)): >=

0,77 mg/l

Exposure time: 72 h

Test Type: Cell multiplication inhibition test

Method: FDA 4.01

according to Regulation (EC) No. 1907/2006



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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)): >

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

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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 (Short-term (acute)

aquatic hazard)

: 1000

Toxicity to fish (Chronic tox-

icity)

: NOEC: 0,0041 mg/l Exposure time: 35 d

Species: Brachydanio rerio (zebrafish)

Test Type: Fish early-life stage (FELS) toxicity test (OECD

210)

Method: OECD Test Guideline 210

GLP: yes

NOEC: 0,0041 mg/l Exposure time: 35 d

Species: Danio rerio (zebra fish) Method: OECD Test Guideline 210

LOEC: > 0,0041 mg/l Exposure time: 35 d

Species: Danio rerio (zebra fish) Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0,0047 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

Test Type: Daphnia reproduction test Method: OECD Test Guideline 211

GLP: yes

LOEC: > 0,0047 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

NOEC: 100 mg/kg Exposure time: 28 d

Species: Chironomus riparius (Midge larvae)
Test Type: Toxicity to sediment dwelling organisms

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Method: OECD Test Guideline 218

GLP: yes

LOEC: > 100 mg/kg

Species: Midge emergence (Chironomus riparius)

Method: OECD Test Guideline 218

EC50: > 100 mg/kg Exposure time: 28 d

Species: Midge emergence (Chironomus riparius)

Method: OECD Test Guideline 218

M-Factor (Long-term (chron-

ic) aquatic hazard)

: 100

Toxicity to bacteria

: 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

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 or-

ganisms

: Test Type: Acute toxicity EC50: > 1 000 mg/kg Exposure time: 14 d

Species: Eisenia fetida (earthworms) Method: OECD Test Guideline 207

GLP:yes

Test Type: Acute toxicity NOEC: 1 000 mg/kg Exposure time: 14 d

Species: Eisenia fetida (earthworms) Method: OECD Test Guideline 207

GLP:yes

according to Regulation (EC) No. 1907/2006



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Test Type: Reproduction Test

EC50: > 1 000 mg/kg Exposure time: 28 d

Species: Springtail (Collembola)

Method: ISO 11267

GLP:yes

Test Type: Reproduction Test

NOEC: 250 mg/kg Exposure time: 28 d

Species: Springtail (Collembola)

Method: ISO 11267

GLP:yes

LOEC: 500 mg/kg Exposure time: 28 d

Species: Springtail (Collembola)

Method: ISO 11267

Plant toxicity

: NOEC: 1 000 mg/kg Exposure time: 16 d

Species: Terestrial plants

Method: OECD Test Guideline 208

GLP: yes

EC50: > 1 000 mg/kg Exposure time: 16 d Species: Terestrial plants

Method: OECD Test Guideline 208

GLP: yes

12.2 Persistence and degradability

Product:

Biodegradability

Test Type: 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: total system 1

Test Type: anaerobic

Degradation half life (DT50): 5,3 d Method: OECD Test Guideline 308

GLP: yes

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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

Test Type: aerobic

Degradation half life (DT50): 2,7 d Method: OECD Test Guideline 308

GLP: yes

Remarks: Fresh water 1

12.3 Bioaccumulative potential

Product:

Bioaccumulation

Species: Oncorhynchus mykiss (rainbow trout)

Exposure time: 28 d

Bioconcentration factor (BCF): 1 433 Method: OECD Test Guideline 305

GLP: yes

Species: Oncorhynchus mykiss (rainbow trout)

Exposure time: 28 d

Bioconcentration factor (BCF): 2 049 Method: OECD Test Guideline 305

GLP: yes

12.4 Mobility in soil

Product:

Distribution among environmental compartments : Adsorption/Soil

Koc: 40428 - 370745Method: OECD Test Guideline 106

Stability in soil

Test Type: Aerobic transformation in soil

Dissipation time: 344 d

Method: OECD Test Guideline 307

GLP: yes

according to Regulation (EC) No. 1907/2006



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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

12.5 Results of PBT and vPvB assessment

Product:

Assessment

: PBT substance.

12.6 Other adverse effects

Product:

Additional ecological infor-

mation

: No data available

Remarks: No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

: Must be incinerated in a suitable incineration plant holding a

permit delivered by the competent authorities.

In accordance with National, Federal, State and Local regula-

tions.

SECTION 14: Transport information

14.1 UN number

ADN

: UN 3077

ADR

: UN 3077

RID

: UN 3077

IMDG

: UN 3077

IATA

UN 3077

14.2 UN proper shipping name

ADN

: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

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N.O.S.

ADR

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(BEDAQUILINE FUMARATE)

RID

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

(BEDAQUILINE FUMARATE)

IMDG

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(BEDAQUILINE FUMARATE)

IATA

Environmentally hazardous substance, solid, n.o.s.

(BEDAQUILINE FUMARATE)

14.3 Transport hazard class(es)

ADN

9

ADR

9

RID

9

IMDG

9

IATA

9

14.4 Packing group

ADN

Packing group

Ш

Classification Code

M7

Hazard Identification Number

90

Labels

Remarks

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 ADR/RID/ADN/IMDG/IATA DGR provided the packagings

Special Provision 375: Environmentally Hazardous

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.

ADR

Packing group

III

Classification Code

M7

Hazard Identification Number

90

Labels

9

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Tunnel restriction code

Remarks

Special Provision 375: 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 ADR/RID/ADN/IMDG/IATA DGR 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.

RID

Packing group

Classification Code

Hazard Identification Number

Labels Remarks Ш

M7 90

Special Provision 375: 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 ADR/RID/ADN/IMDG/IATA DGR 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.

IMDG

Packing group Labels

EmS Code

Remarks

Ш 9

F-A, S-F

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

according to Regulation (EC) No. 1907/2006



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solids and provided packaging provisions of ADR/RID/ADN/IMDG §3.5.1.4 are met.

IATA (Cargo)

Packing instruction (cargo

aircraft)

Packing instruction (LQ)
Packing instruction (EQ)

Packing group Labels

Remarks

956

Y956 E1 III

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.

IATA (Passenger)

Packing instruction

(passenger aircraft)

Packing instruction (LQ)
Packing group

Labels

Remarks

956

Y956

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: 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.

14.5 Environmental hazards

ADN

Environmentally hazardous

yes

ADR

Environmentally hazardous

yes

according to Regulation (EC) No. 1907/2006



BEDAQUILINE FUMARATE

Version 1.64

Revision Date: 2019-04-23

SDS Number: 100000003349 Date of last issue: 2018-10-17 Date of first issue: 2012-01-10

RID

Environmentally hazardous

yes

Marine pollutant

yes

IATA (Passenger)

Marine pollutant

yes

IATA (Cargo)

Marine pollutant

yes

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

E1

ENVIRONMENTAL HAZARDS

Quantity 1 100 t

Quantity 2 200 t

15.2 Chemical safety assessment

A Chemical Safety Assessment is not required for this substance.

SECTION 16: Other information

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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