

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fidaxomicin Solid Formulation

Version 2.2 Revision Date: 2023/09/30 SDS Number: 4750793-00009 Date of last issue: 2023/04/04
Date of first issue: 2019/08/15

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Fidaxomicin Solid Formulation

Manufacturer or supplier's details

Company : MSD

Address : 199 Wenhai North Road
HEDA, Hangzhou - Zhejiang Province - CHINA 310018

Telephone : 908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance : granules
Colour : White to light yellow
Odour : No data available

Harmful if swallowed.

GHS Classification

Acute toxicity (Oral) : Category 4

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H302 Harmful if swallowed.

Precautionary statements : **Prevention:**
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fidaxomicin Solid Formulation

Version 2.2 Revision Date: 2023/09/30 SDS Number: 4750793-00009 Date of last issue: 2023/04/04
Date of first issue: 2019/08/15

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.

Disposal:

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

Physical and chemical hazards

Not classified based on available information.

Health hazards

Harmful if swallowed.

Environmental hazards

Not classified based on available information.

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Fidaxomicin	873857-62-6	>= 50 -< 70
Cellulose	9004-34-6	>= 20 -< 30
Sodium benzoate	532-32-1	>= 1 -< 10
Citric acid	77-92-9	>= 1 -< 10

4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.
- In case of skin contact : Wash with water and soap.
Get medical attention if symptoms occur.
- In case of eye contact : If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel.
Get medical attention.
Rinse mouth thoroughly with water.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fidaxomicin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.2	2023/09/30	4750793-00009	Date of first issue: 2019/08/15

Most important symptoms and effects, both acute and delayed	:	Never give anything by mouth to an unconscious person. Harmful if swallowed. Contact with dust can cause mechanical irritation or drying of the skin.
Protection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Metal oxides Chlorine compounds
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fidaxomicin Solid Formulation

Version 2.2 Revision Date: 2023/09/30 SDS Number: 4750793-00009 Date of last issue: 2023/04/04
Date of first issue: 2019/08/15

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Handling

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.
- Avoidance of contact : Oxidizing agents

Storage

- Conditions for safe storage : Keep in properly labelled containers.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
- Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Fidaxomicin	873857-62-6	TWA	200 µg/m ³ (OEB 2)	Internal
Cellulose	9004-34-6	PC-TWA	10 mg/m ³	CN OEL

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fidaxomicin Solid Formulation

Version 2.2 Revision Date: 2023/09/30 SDS Number: 4750793-00009 Date of last issue: 2023/04/04
Date of first issue: 2019/08/15

		TWA	10 mg/m ³	ACGIH
Sodium benzoate	532-32-1	TWA (Inhalable particulate matter)	2.5 mg/m ³	ACGIH

Engineering measures : Use feasible engineering controls to minimize exposure to compound.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Eye/face protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.

Hand protection

Material : Chemical-resistant gloves

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.

When using do not eat, drink or smoke.

Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : granules

Colour : White to light yellow

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fidaxomicin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.2	2023/09/30	4750793-00009	Date of first issue: 2019/08/15

Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
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SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fidaxomicin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.2	2023/09/30	4750793-00009	Date of first issue: 2019/08/15

Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes	:	Inhalation Skin contact Ingestion Eye contact
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Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity	:	Acute toxicity estimate: 875.04 mg/kg Method: Calculation method
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Components:

Fidaxomicin:

Acute oral toxicity	:	LD50 (Rat): > 1,000 mg/kg LD50 (Dog): > 120 mg/kg
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Acute toxicity (other routes of administration)	:	LD50 (Rat): 200 mg/kg Application Route: Intravenous
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Cellulose:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg

Sodium benzoate:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg Assessment: The substance or mixture has no acute oral toxicity
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fidaxomicin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.2	2023/09/30	4750793-00009	Date of first issue: 2019/08/15

Remarks: Based on data from similar materials

Citric acid:

Acute oral toxicity : LD50 (Mouse): 5,400 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation

Not classified based on available information.

Components:

Sodium benzoate:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Citric acid:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Sodium benzoate:

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405

Citric acid:

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fidaxomicin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.2	2023/09/30	4750793-00009	Date of first issue: 2019/08/15

Components:

Sodium benzoate:

Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Result : negative
Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

Fidaxomicin:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Result: positive

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Application Route: Intravenous
Result: negative

Test Type: comet assay
Species: Rat
Result: negative

Cellulose:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Sodium benzoate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fidaxomicin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.2	2023/09/30	4750793-00009	Date of first issue: 2019/08/15

Test Type: Chromosome aberration test in vitro
Result: positive

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative

Citric acid:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: in vitro micronucleus test
Result: positive

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Cellulose:

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

Sodium benzoate:

Species : Rat
Application Route : Ingestion
Exposure time : 24 month(s)
Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

Fidaxomicin:

Effects on fertility : Test Type: Fertility/early embryonic development

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fidaxomicin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.2	2023/09/30	4750793-00009	Date of first issue: 2019/08/15

Species: Rat
Application Route: Intravenous injection
Fertility: NOAEL: 6.3 mg/kg body weight

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Intravenous injection
Developmental Toxicity: NOAEL: 12.6 mg/kg body weight
Remarks: No significant adverse effects were reported

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Intravenous injection
Developmental Toxicity: NOAEL: 7 mg/kg body weight
Remarks: No significant adverse effects were reported

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

Sodium benzoate:

Effects on fertility : Test Type: Four-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

Citric acid:

Effects on foetal development : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

STOT - single exposure

Not classified based on available information.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fidaxomicin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.2	2023/09/30	4750793-00009	Date of first issue: 2019/08/15

Components:

Citric acid:

Assessment : May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Fidaxomicin:

Species : Rat
NOAEL : 90 mg/kg
Application Route : Oral
Exposure time : 28 D
Remarks : No significant adverse effects were reported

Species : Rat
NOAEL : 62.5 mg/kg
Application Route : Intravenous
Exposure time : 14 D

Species : Dog
NOAEL : 9,600 mg/kg
Application Route : Oral
Exposure time : 3 M
Symptoms : Vomiting
Remarks : No significant adverse effects were reported

Species : Monkey
NOAEL : 90 mg/kg
Application Route : Oral
Exposure time : 28 D
Remarks : No significant adverse effects were reported

Species : Juvenile rat
NOAEL : 200 mg/kg
Application Route : Oral
Exposure time : 28 D
Remarks : No significant adverse effects were reported

Cellulose:

Species : Rat
NOAEL : $\geq 9,000$ mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Sodium benzoate:

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fidaxomicin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.2	2023/09/30	4750793-00009	Date of first issue: 2019/08/15

Species : Rat
NOAEL : 1,000 mg/kg
Application Route : Ingestion
Exposure time : 24 Months

Citric acid:

Species : Rat
NOAEL : 4,000 mg/kg
LOAEL : 8,000 mg/kg
Application Route : Ingestion
Exposure time : 10 Days

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Fidaxomicin:

Ingestion : Symptoms: Abdominal pain, Nausea, Vomiting, constipation

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Fidaxomicin:

Toxicity to algae/aquatic plants : EC50 (Anabaena flos-aquae (cyanobacterium)): > 18.4 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

NOEC (Anabaena flos-aquae (cyanobacterium)): 5.8 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 8.91 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 19.6 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: > 50 mg/l
Exposure time: 3 h

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fidaxomicin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.2	2023/09/30	4750793-00009	Date of first issue: 2019/08/15

Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 5.9 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Cellulose:

Toxicity to fish : LC50 (*Oryzias latipes* (Japanese medaka)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Sodium benzoate:

Toxicity to fish : LC50 (*Pimephales promelas* (fathead minnow)): 484 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): > 100 mg/l
Exposure time: 96 h

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

NOEC (*Pseudokirchneriella subcapitata* (green algae)): 32 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Citric acid:

Toxicity to fish : LC50 (*Pimephales promelas* (fathead minnow)): > 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 1,535 mg/l
Exposure time: 24 h

Persistence and degradability

Components:

Cellulose:

Biodegradability : Result: Readily biodegradable.

Sodium benzoate:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 75 %
Exposure time: 28 d

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fidaxomicin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.2	2023/09/30	4750793-00009	Date of first issue: 2019/08/15

Citric acid:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 97 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Bioaccumulative potential

Components:

Fidaxomicin:

Partition coefficient: n-octanol/water : log Pow: 4.4

Sodium benzoate:

Partition coefficient: n-octanol/water : log Pow: 1.88

Citric acid:

Partition coefficient: n-octanol/water : log Pow: -1.72

Mobility in soil

Components:

Fidaxomicin:

Distribution among environmental compartments : log Koc: 0.80

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fidaxomicin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.2	2023/09/30	4750793-00009	Date of first issue: 2019/08/15

Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo aircraft) : Not applicable
Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

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

Not applicable for product as supplied.

National Regulations

GB 6944/12268

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

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

AICS : not determined

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fidaxomicin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.2	2023/09/30	4750793-00009	Date of first issue: 2019/08/15

DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Revision Date : 2023/09/30

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CN OEL : Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.

ACGIH / TWA : 8-hour, time-weighted average
CN OEL / PC-TWA : Permissible concentration - time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Sub-

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fidaxomicin Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
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stances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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