

# SAFETY DATA SHEET



## Fidaxomicin Solid Formulation

Version 4.0      Revision Date: 14.04.2025      SDS Number: 4750803-00011      Date of last issue: 06.04.2024  
Date of first issue: 15.08.2019

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

#### 1.1 Product identifier

Trade name : Fidaxomicin Solid Formulation

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

Use of the Substance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
117 16th Road  
1685 Halfway house, Midrand, South Africa

Telephone : +27 11 655 3000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4      H302: Harmful if swallowed.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

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.

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### Response:

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

Hazardous components which must be listed on the label:

Fidaxomicin

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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.

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## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Fidaxomicin	873857-62-6	Acute Tox. 4; H302	>= 50 - < 70
Sodium benzoate	532-32-1 208-534-8	Eye Irrit. 2; H319	>= 1 - < 10
Citric acid	77-92-9 201-069-1 607-750-00-3	Eye Irrit. 2; H319 STOT SE 3; H335	>= 1 - < 10

For explanation of abbreviations see section 16.

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## SECTION 4: First aid measures

### 4.1 Description of 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.

Protection of first-aiders : 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).

If inhaled : If inhaled, remove to fresh air.

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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.  
Never give anything by mouth to an unconscious person.

**4.2 Most important symptoms and effects, both acute and delayed**

Risks : Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.

Harmful if swallowed.

**4.3 Indication of any immediate medical attention and special treatment needed**

Treatment : Treat symptomatically and supportively.

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**SECTION 5: Firefighting measures****5.1 Extinguishing media**

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

**5.2 Special hazards arising from the substance or mixture**

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Metal oxides  
Chlorine compounds

**5.3 Advice for firefighters**

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

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.

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Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**6.2 Environmental precautions**

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.

**6.3 Methods and material for containment and cleaning up**

Methods for 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.  
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.

**6.4 Reference to other sections**

See sections: 7, 8, 11, 12 and 13.

**SECTION 7: Handling and storage****7.1 Precautions for safe 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 as-

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Hygiene measures	<p>sessment 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.</p> <p>: 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.</p> <p>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.</p>
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### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	: Keep in properly labelled containers. Store in accordance with the particular national regulations.
Advice on common storage	: Do not store with the following product types: Strong oxidizing agents

### 7.3 Specific end use(s)

Specific use(s)	: No data available
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## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Fidaxomicin	873857-62-6	TWA	200 µg/m3 (OEB 2)	Internal
Cellulose	9004-34-6	OEL-RL	10 mg/m3	ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				

#### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium benzoate	Workers	Inhalation	Long-term systemic effects	3 mg/m3
	Workers	Inhalation	Long-term local effects	0,1 mg/m3
	Workers	Skin contact	Long-term systemic effects	62,5 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	1,5 mg/m3

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	Consumers	Inhalation	Long-term local effects	0,06 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	31,25 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	16,6 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
Citric acid	Fresh water	0,44 mg/l
	Marine water	0,044 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	34,6 mg/kg dry weight (d.w.)
	Marine sediment	3,46 mg/kg dry weight (d.w.)
	Soil	33,1 mg/kg dry weight (d.w.)
Sodium citrate	Fresh water	0,44 mg/l
	Marine water	0,044 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	34,6 mg/kg dry weight (d.w.)
	Marine water	3,46 mg/kg dry weight (d.w.)
	Soil	31,1 mg/kg dry weight (d.w.)
Sodium benzoate	Fresh water	0,13 mg/l
	Freshwater - intermittent	0,305 mg/l
	Marine water	0,013 mg/l
	Sewage treatment plant	10 mg/l
	Fresh water sediment	1,76 mg/kg dry weight (d.w.)
	Marine sediment	0,176 mg/kg dry weight (d.w.)
Oral (Secondary Poisoning)	Soil	0,276 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	300 mg/kg food

## 8.2 Exposure controls

### 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

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.

Hand protection  
Material : Chemical-resistant gloves

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Skin and body protection	:	Work uniform or laboratory coat.
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 (P)

**SECTION 9: Physical and chemical properties****9.1 Information on basic 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
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

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Explosive properties : Not explosive  
Oxidizing properties : The substance or mixture is not classified as oxidizing.

### 9.2 Other information

Molecular weight : No data available  
Particle size : No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

||| Harmful if swallowed.

#### Product:

Acute oral toxicity : Acute toxicity estimate: 875,04 mg/kg  
Method: Calculation method

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Acute oral toxicity	:	LD50 (Rat): > 1.000 mg/kg
		LD50 (Dog): > 120 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Rat): 200 mg/kg Application Route: Intravenous

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

**Citric acid:**

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

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**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

**Sodium benzoate:**

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

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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:****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 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

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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
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**STOT - single exposure**

Not classified based on available information.
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**Components:****Citric acid:**

Assessment	: May cause respiratory irritation.
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**STOT - repeated exposure**

Not classified based on available information.
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**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

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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

### **Sodium benzoate:**

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

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## SECTION 12: Ecological information

### 12.1 Toxicity

#### **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 microorganisms : EC50 : > 50 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition

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Method: OECD Test Guideline 209

NOEC : 5,9 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : NOEC: 8,91 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210  
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 19,6 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

**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

**12.2 Persistence and degradability****Components:****Sodium benzoate:**

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

**Citric acid:**

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

### 12.3 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

### 12.4 Mobility in soil

#### Components:

##### **Fidaxomicin:**

Distribution among environmental compartments : log Koc: 0,80

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Other adverse effects

#### Product:

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

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### SECTION 14: Transport information

#### 14.1 UN number

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA** : Not regulated as a dangerous good

#### 14.2 UN proper shipping name

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA** : Not regulated as a dangerous good

#### 14.3 Transport hazard class(es)

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA** : Not regulated as a dangerous good

#### 14.4 Packing group

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA (Cargo)** : Not regulated as a dangerous good  
**IATA (Passenger)** : Not regulated as a dangerous good

#### 14.5 Environmental hazards

Not regulated as a dangerous good

#### 14.6 Special precautions for user

Not applicable

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

Remarks : Not applicable for product as supplied.

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**SECTION 15: Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****The components of this product are reported in the following inventories:**

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

**15.2 Chemical safety assessment**

A Chemical Safety Assessment has not been carried out.

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**SECTION 16: Other information**

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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**Full text of H-Statements**

H302	:	Harmful if swallowed.
H319	:	Causes serious eye irritation.
H335	:	May cause respiratory irritation.

**Full text of other abbreviations**

Acute Tox.	:	Acute toxicity
Eye Irrit.	:	Eye irritation
STOT SE	:	Specific target organ toxicity - single exposure
ZA OEL	:	South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits
ZA OEL / OEL-RL	:	Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 popula-

# SAFETY DATA SHEET



## Fidaxomicin Solid Formulation

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4.0

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tion; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; 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

### 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/>

### Classification of the mixture:

Acute Tox. 4

H302

### Classification procedure:

Calculation method

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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