

## Fidaxomicin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
3.0	18.06.2025	1731986-00016	Date of first issue: 05.06.2017

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## Section 1: Identification

**Product identifier** : Fidaxomicin Formulation

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

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

**Manufacturer or supplier's details**


Company : MSD  
Address : 50 Tuas West Drive  
Singapore - Singapore 638408  
Telephone : +1-908-740-4000  
Emergency telephone number : 65 6697 2111 (24/7/365)  
E-mail address : EHSDATASTEWARD@msd.com

## Section 2: Hazard identification

**Classification of the substance or mixture**

Acute toxicity (Oral) : Category 4

**GHS Label elements, including precautionary statements**

Hazard pictograms	:	
Signal word	:	Warning
Hazard statements	:	H302 Harmful if swallowed.
Precautionary statements	:	<b>Prevention:</b> P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. <b>Response:</b> P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth. <b>Disposal:</b> P501 Dispose of contents/ container to an approved waste disposal plant.

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## Other hazards which do not result in classification

None known.

## Section 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	>= 30 -< 50
Starch	9005-25-8	>= 10 -< 20

## Section 4: First-aid measures

## Description of necessary 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 as a precaution.  
Get medical attention if symptoms occur.

In case of eye contact : Flush eyes with water as a precaution.  
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.

## Most important symptoms and effects, both acute and delayed

Risks : Harmful if swallowed.

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).

## Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

## Section 5: Fire-fighting measures

## Extinguishing media

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

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Unsuitable extinguishing media : None known.

**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

**Special protective actions for fire-fighters**

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

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**Section 6: Accidental release measures****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).

**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.

**Methods and materials for containment and cleaning up**

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal. 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.

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**Section 7: Handling and storage****Precautions for safe handling**

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- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : 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  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- 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.

**Conditions for safe storage, including any incompatibilities**

- 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

**Section 8: Exposure controls/personal protection****Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Fidaxomicin	873857-62-6	TWA	200 µg/m <sup>3</sup> (OEB 2)	Internal
Cellulose	9004-34-6	PEL (long term)	10 mg/m <sup>3</sup>	SG OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Starch	9005-25-8	PEL (long term)	10 mg/m <sup>3</sup>	SG OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH

- Appropriate engineering control measures** : Ensure adequate ventilation, especially in confined areas.  
Minimize workplace exposure concentrations.

**Individual protection measures, such as personal protective equipment (PPE)**

- Eye/face protection : Wear the following personal protective equipment:  
Safety glasses
- Skin protection : Skin should be washed after contact.
- Respiratory protection : If adequate local exhaust ventilation is not available or expo-

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sure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

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**Section 9: Physical and chemical properties**

Appearance : solid

Colour : white to off-white

Odour : No data available

Odour Threshold : No data available

pH : Not applicable

|| Melting point/freezing point : 175 - 185 °C

Initial boiling point and boiling range : Not applicable

Flash point : Not applicable

Evaporation rate : No data available

Flammability (solid, gas) : Not classified as a flammability hazard

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 : No data available

Relative vapour density : No data available

Density : No data available

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Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: log Pow: 4.4 Active ingredient
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, kinematic	: No data available
Explosive properties	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.
Molecular weight	: Not applicable
Particle characteristics	
Particle size	: No data available

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**Section 10: Stability and reactivity**

Reactivity	: Not classified as a reactivity hazard.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: Can react with strong oxidizing agents.
Conditions to avoid	: None known.
Incompatible materials	: Oxidizing agents
Hazardous decomposition products	: No hazardous decomposition products are known.

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**Section 11: Toxicological information**

Information on likely routes of exposure	: Skin contact Ingestion Eye contact
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**Acute toxicity**

Harmful if swallowed.

**Product:**

Acute oral toxicity	: Acute toxicity estimate: 833.33 mg/kg Method: Calculation method
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**Components:****Fidaxomicin:**

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

**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

**Starch:**

Acute oral toxicity	: LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity	: LD50 (Rabbit): > 2,000 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Starch:**

Species	: Rabbit
Result	: No eye irritation

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

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Starch:**

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Result	: negative

**Germ cell mutagenicity**

Not classified based on available information.

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**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

**Starch:**

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

Not classified based on available information.

**Components:****Cellulose:**

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

**Reproductive toxicity**

Not classified based on available information.



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**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

**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

**STOT - single exposure**

Not classified based on available information.

**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

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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

**Starch:**

Species	: Rat
NOAEL	: $\geq 2,000$ mg/kg
Application Route	: Skin contact
Exposure time	: 28 Days
Method	: OECD Test Guideline 410

**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****Toxicity****Components:****Fidaxomicin:**

Toxicity to algae/aquatic	: EC50 (Anabaena flos-aquae (cyanobacterium)): $> 18.4$ mg/l
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plants	:	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 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
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**Persistence and degradability****Components:****Cellulose:**

Biodegradability	:	Result: Readily biodegradable.
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**Bioaccumulative potential****Components:****Fidaxomicin:**

Partition coefficient: n-octanol/water	:	log Pow: 4.4
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**Mobility in soil****Components:****Fidaxomicin:**

Distribution among environmental compartments : log K<sub>oc</sub>: 0.80

**Other adverse effects**

No data available

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**Section 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.

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**Section 14: Transport information****International Regulations****UNRTDG**

UN number	:	Not applicable
UN proper shipping name	:	Not applicable
Transport hazard class(es)	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Environmentally hazardous	:	no

**IATA-DGR**

UN/ID No.	:	Not applicable
UN proper shipping name	:	Not applicable
Transport hazard class(es)	:	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
UN proper shipping name	:	Not applicable
Transport hazard class(es)	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable

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Marine pollutant : Not applicable

**Transport in bulk according to IMO instruments**

Not applicable for product as supplied.

**Special precautions for user**

Not applicable

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**Section 15: Regulatory information****Safety, health and environmental regulations specific for the product in question**

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subject to the requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable  
Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable  
Regulations

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

AICS : not determined

DSL : not determined

IECSC : not determined

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**Section 16: Other information**

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**Further information**

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

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

Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
SG OEL : Singapore. Workplace Safety and Health (General Provisions)  
Regulations - First Schedule Permissible Exposure Limits of  
Toxic Substances.

ACGIH / TWA : 8-hour, time-weighted average  
SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

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 -

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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 Substances 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

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

SG / EN