

SAFETY DATA SHEET



Fidaxomicin Solid Formulation

Version 8.0 Revision Date: 2025/04/14 SDS Number: 4750797-00013 Date of last issue: 2024/09/28
Date of first issue: 2019/08/15

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Fidaxomicin Solid Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.
Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

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.

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.

SAFETY DATA SHEET



Fidaxomicin Solid Formulation

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 8.0 | Revision Date: 2025/04/14 | SDS Number: 4750797-00013 | Date of last issue: 2024/09/28 Date of first issue: 2019/08/15 |
|----------------|------------------------------|------------------------------|---|

Other hazards which do not result in classification

Important symptoms and outlines of the emergency assumed : 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) | ENCS No. |
|------------------|-------------|-----------------------|----------------|
| Fidaxomicin | 873857-62-6 | >= 50 - < 60 | - |
| Cellulose | 9004-34-6 | >= 20 - < 30 | |
| Sodium benzoate | 532-32-1 | >= 1 - < 10 | 3-1293, 3-1272 |
| Citric acid | 77-92-9 | >= 1 - < 10 | 2-1318 |
| Propylene glycol | 57-55-6 | >= 0.1 - < 1 | 2-234 |

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.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed : 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.

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).

Notes to physician : Treat symptomatically and supportively.

SAFETY DATA SHEET



Fidaxomicin Solid Formulation

Version
8.0

Revision Date:
2025/04/14

SDS Number:
4750797-00013

Date of last issue: 2024/09/28
Date of first issue: 2019/08/15

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
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.
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.

SAFETY DATA SHEET



Fidaxomicin Solid Formulation

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 8.0 | Revision Date: 2025/04/14 | SDS Number: 4750797-00013 | Date of last issue: 2024/09/28 Date of first issue: 2019/08/15 |
|----------------|------------------------------|------------------------------|---|

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

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.

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

Threshold limit value and permissible exposure limits for each component in the work environment

SAFETY DATA SHEET



Fidaxomicin Solid Formulation

Version
8.0

Revision Date:
2025/04/14

SDS Number:
4750797-00013

Date of last issue: 2024/09/28
Date of first issue: 2019/08/15

| Components | CAS-No. | Value type (Form of exposure) | Control parame- ters / Concentra- tion standard / Permissible con- centration | Basis |
|-----------------|-------------|--|---|----------|
| Fidaxomicin | 873857-62-6 | TWA | 200 µg/m ³ (OEB 2) | Internal |
| Cellulose | 9004-34-6 | TWA | 10 mg/m ³ | ACGIH |
| Sodium benzoate | 532-32-1 | TWA (Inhal- able particu- late 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

Hand protection : Chemical-resistant gloves

Material : Chemical-resistant gloves

Eye 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : granules

Colour : White to light yellow

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

SAFETY DATA SHEET



Fidaxomicin Solid Formulation

Version 8.0 Revision Date: 2025/04/14 SDS Number: 4750797-00013 Date of last issue: 2024/09/28
Date of first issue: 2019/08/15

| | |
|--|--|
| Flammability (liquids) | : No data available |
| Lower explosion limit and upper explosion limit / flammability limit | |
| Upper explosion limit / Up- per flammability limit | : No data available |
| Lower explosion limit / | : No data available |
| Lower flammability limit | |
| Flash point | : Not applicable |
| Decomposition temperature | : No data available |
| pH | : No data available |
| Evaporation rate | : Not applicable |
| Auto-ignition temperature | : No data available |
| Viscosity | |
| Viscosity, kinematic | : Not applicable |
| Solubility(ies) | |
| Water solubility | : No data available |
| Partition coefficient: n- octanol/water | : Not applicable |
| Vapour pressure | : Not applicable |
| Density and / or relative density | |
| Relative density | : No data available |
| Density | : No data available |
| Relative vapour density | : Not applicable |
| Explosive properties | : Not explosive |
| Oxidizing properties | : The substance or mixture is not classified as oxidizing. |
| Molecular weight | : No data available |
| Particle characteristics | |
| Particle size | : No data available |

10. STABILITY AND REACTIVITY

| | |
|--------------------|--|
| Reactivity | : Not classified as a reactivity hazard. |
| Chemical stability | : Stable under normal conditions. |

SAFETY DATA SHEET



Fidaxomicin Solid Formulation

Version 8.0 Revision Date: 2025/04/14 SDS Number: 4750797-00013 Date of last issue: 2024/09/28
Date of first issue: 2019/08/15

| | |
|------------------------------------|--|
| 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

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

Components:

Fidaxomicin:

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

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
Remarks: Based on data from similar materials

SAFETY DATA SHEET



Fidaxomicin Solid Formulation

Version
8.0

Revision Date:
2025/04/14

SDS Number:
4750797-00013

Date of last issue: 2024/09/28
Date of first issue: 2019/08/15

||

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 |

Propylene glycol:

| | | |
|---------------------------|---|---|
| Acute oral toxicity | : | LD50 (Rat): 22,000 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): > 44.9 mg/l Exposure time: 4 h Test atmosphere: dust/mist |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg 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 |

Propylene glycol:

| | | |
|---------|---|-------------------------|
| 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 |

SAFETY DATA SHEET



Fidaxomicin Solid Formulation

Version
8.0

Revision Date:
2025/04/14

SDS Number:
4750797-00013

Date of last issue: 2024/09/28
Date of first issue: 2019/08/15

Citric acid:

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

Propylene glycol:

| | | |
|---------|---|-------------------------|
| Species | : | Rabbit |
| Result | : | No eye irritation |
| 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.

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 |

Propylene glycol:

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

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 |

Fidaxomicin Solid Formulation

Version 8.0

Revision Date: 2025/04/14

SDS Number: 4750797-00013

Date of last issue: 2024/09/28
Date of first issue: 2019/08/15

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

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

Propylene glycol:

Fidaxomicin Solid FormulationVersion
8.0Revision Date:
2025/04/14SDS Number:
4750797-00013Date of last issue: 2024/09/28
Date of first issue: 2019/08/15

| | |
|-----------------------|--|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) Result: negative |
| | Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative |
| Genotoxicity in vivo | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection 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 |

Propylene glycol:

| | |
|-------------------|-------------|
| Species | : Rat |
| Application Route | : Ingestion |
| Exposure time | : 2 Years |
| 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 |

Fidaxomicin Solid Formulation

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 8.0 | Revision Date: 2025/04/14 | SDS Number: 4750797-00013 | Date of last issue: 2024/09/28 Date of first issue: 2019/08/15 |
|----------------|------------------------------|------------------------------|---|

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 |
|-------------------------------|---|

Propylene glycol:

| | |
|-------------------------------|---|
| Effects on fertility | : Test Type: Two-generation reproduction toxicity study Species: Mouse Application Route: Ingestion Result: negative |
| Effects on foetal development | : Test Type: Embryo-foetal development Species: Mouse Application Route: Ingestion Result: negative |

SAFETY DATA SHEET



Fidaxomicin Solid Formulation

Version
8.0

Revision Date:
2025/04/14

SDS Number:
4750797-00013

Date of last issue: 2024/09/28
Date of first issue: 2019/08/15

STOT - single exposure

Not classified based on available information.

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 | : | >= 9,000 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |

SAFETY DATA SHEET



Fidaxomicin Solid Formulation

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 8.0 | Revision Date: 2025/04/14 | SDS Number: 4750797-00013 | Date of last issue: 2024/09/28 Date of first issue: 2019/08/15 |
|----------------|------------------------------|------------------------------|---|

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 |

Propylene glycol:

| | | |
|-------------------|---|----------------|
| Species | : | Rat, male |
| NOAEL | : | >= 1,700 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 2 yr |

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 |

SAFETY DATA SHEET



Fidaxomicin Solid Formulation

Version
8.0

Revision Date:
2025/04/14

SDS Number:
4750797-00013

Date of last issue: 2024/09/28
Date of first issue: 2019/08/15

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

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

Propylene glycol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
Exposure time: 96 h

SAFETY DATA SHEET



Fidaxomicin Solid Formulation

Version 8.0 Revision Date: 2025/04/14 SDS Number: 4750797-00013 Date of last issue: 2024/09/28
Date of first issue: 2019/08/15

| | | |
|--|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l Exposure time: 7 d |
| Toxicity to microorganisms | : | NOEC (Pseudomonas putida): > 20,000 mg/l Exposure time: 18 h |

Persistence and degradability

Components:

Cellulose:

| | | |
|------------------|---|--------------------------------|
| Biodegradability | : | Result: Readily biodegradable. |
|------------------|---|--------------------------------|

Sodium benzoate:

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

Citric acid:

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

Propylene glycol:

| | | |
|------------------|---|---|
| Biodegradability | : | Result: Readily biodegradable. Biodegradation: 98.3 % Exposure time: 28 d Method: OECD Test Guideline 301F |
|------------------|---|---|

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:

SAFETY DATA SHEET



Fidaxomicin Solid Formulation

Version 8.0 Revision Date: 2025/04/14 SDS Number: 4750797-00013 Date of last issue: 2024/09/28
Date of first issue: 2019/08/15

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

Propylene glycol:

Partition coefficient: n-octanol/water : log Pow: -1.07
Method: Regulation (EC) No. 440/2008, Annex, A.8

Mobility in soil

Components:

Fidaxomicin:

Distribution among environmental compartments : log Koc: 0.80

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.

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
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Environmentally hazardous : no

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

SAFETY DATA SHEET



Fidaxomicin Solid Formulation

Version 8.0 Revision Date: 2025/04/14 SDS Number: 4750797-00013 Date of last issue: 2024/09/28
Date of first issue: 2019/08/15

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

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Priority Assessment Chemical Substance

| Chemical name | Number |
|------------------|--------|
| Propane-1,2-diol | 106 |

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Not applicable

SAFETY DATA SHEET



Fidaxomicin Solid Formulation

Version 8.0 Revision Date: 2025/04/14 SDS Number: 4750797-00013 Date of last issue: 2024/09/28
Date of first issue: 2019/08/15

Substances Subject to Indicated Names

Not applicable

Skin and Eye Damage Substances (ISHL MO Art. 594-2)

Not applicable

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Not regulated as a dangerous good

Aviation Law

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

SAFETY DATA SHEET



Fidaxomicin Solid Formulation

Version
8.0

Revision Date:
2025/04/14

SDS Number:
4750797-00013

Date of last issue: 2024/09/28
Date of first issue: 2019/08/15

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

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/>

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, 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; KECL - 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, Evalu-

SAFETY DATA SHEET



Fidaxomicin Solid Formulation

Version
8.0

Revision Date:
2025/04/14

SDS Number:
4750797-00013

Date of last issue: 2024/09/28
Date of first issue: 2019/08/15

tion, 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.

JP / EN