SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Fidaxomicin Solid Formulation

Manufacturer or supplier’s details
Company name of supplier : MSD
Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

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.
Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth.
Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

Other hazards
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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture
Components
SECTION 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: Harmful if swallowed. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

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.

SECTION 5. FIRE-FIGHTING 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: In the event of fire, wear self-contained breathing apparatus.
for fire-fighters

Use personal protective equipment.

SECTION 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.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

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.

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 decontamination and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

**Conditions for safe storage**
- Keep in properly labeled 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

#### Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fidaxomicin</td>
<td>873857-62-6</td>
<td>TWA</td>
<td>200 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>VLE-PPT</td>
<td>10 mg/m³</td>
<td>NOM-010- STPS-2014</td>
</tr>
</tbody>
</table>

**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**
- 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 facemask 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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**
- Granules

**Color**
- White to light yellow

**Odor**
- No data available
Odor 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
Vapor pressure : Not applicable
Relative vapor 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
Autoignition 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

SECTION 10. STABILITY AND REACTIVITY
Reactivity: Not classified as a reactivity hazard.
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.

SECTION 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
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 sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Sodium benzoate:
Test Type: Local lymph node assay (LLNA)
Routes of exposure: Skin contact
SAFETY DATA SHEET

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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

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

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

**Citric acid:**
Effects on fetal development: Test Type: One-generation reproduction toxicity study
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
### SAFETY DATA SHEET

**Fidaxomicin Solid Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>09.04.2021</td>
<td>4750798-00003</td>
<td>10.10.2020</td>
<td>15.08.2019</td>
</tr>
</tbody>
</table>

#### 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

#### 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
SECTION 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
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

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
SAFETY DATA SHEET

Fidaxomicin Solid Formulation

Version 1.2
Revision Date: 09.04.2021
SDS Number: 4750798-00003
Date of last issue: 10.10.2020
Date of first issue: 15.08.2019

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : 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.

SECTION 14. TRANSPORT INFORMATION

International Regulations
UNRTDG
Not regulated as a dangerous good
IATA-DGR
Not regulated as a dangerous good
IMDG-Code
Not regulated as a dangerous good
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation
NOM-002-SCT
Not regulated as a dangerous good
Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills:
Not applicable

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined
SECTION 16. OTHER INFORMATION

Full text of other abbreviations:

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA: 8-hour, time-weighted average
NOM-010-STPS-2014 / VLE-PPT: Time weighted average limit value

AIC: - 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
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 Chemicals in China
IEC: - International Organisation for Standardization
KCI: - 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
NBE: - Chilean Norm
NO(A)EC: - No Observed (Adverse) Effect Concentration
NO(A)EL: - No Observed (Adverse) Effect Level
NOELR: - No Observable Effect Loading Rate
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
SDAT: - Self-Accelerating Decomposition Temperature
SDS: - Safety Data Sheet
TDG: - Transportation of Dangerous Goods
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

Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 09.04.2021

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.