SECTION 1. IDENTIFICATION

Product name : Fidaxomicin Solid Formulation

Manufacturer or supplier's details
Company : MSD
Address : 855 Leandro N. Alem St., 8 Floor
Buenos Aires, Argentina C1001AFB
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/ doctor if you feel unwell. Rinse mouth.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

**Substance / Mixture:** Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fidaxomicin</td>
<td>873857-62-6</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td></td>
<td>Sodium benzoate</td>
<td>532-32-1</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td></td>
<td>Citric acid</td>
<td>77-92-9</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

**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 firefighting:** 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 fire-fighters: In the event of fire, wear self-contained breathing apparatus. 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.
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>CMP</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</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 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.  
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.

**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

### 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.
SAFETY DATA SHEET

Fidaxomicin Solid Formulation

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
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:**

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

Fidaxomicin Solid Formulation

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

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:**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Method Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EC50 (Anabaena flos-aquae (cyanobacterium)): &gt; 18.4 mg/l</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>NOEC (Anabaena flos-aquae (cyanobacterium)): 5.8 mg/l</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC (Pimephales promelas (fathead minnow)): 8.91 mg/l</td>
<td>OECD Test Guideline 210</td>
</tr>
<tr>
<td></td>
<td>NOEC (Daphnia magna (Water flea)): 19.6 mg/l</td>
<td>OECD Test Guideline 211</td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>EC50: &gt; 50 mg/l</td>
<td>OECD Test Guideline 209</td>
</tr>
<tr>
<td></td>
<td>NOEC: 5.9 mg/l</td>
<td>OECD Test Guideline 209</td>
</tr>
<tr>
<td>Cellulose</td>
<td>LC50 (Oryzias latipes (Japanese medaka)): &gt; 100 mg/l</td>
<td>OECD Test Guideline 209</td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td>LC50 (Pimephales promelas (fathead minnow)): 484 mg/l</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l</td>
<td>OECD Test Guideline 211</td>
</tr>
<tr>
<td></td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 100 mg/l</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

*Remarks:*

- No toxicity at the limit of solubility.
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
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.

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Argentina. Carcinogenic Substances and Agents Registry: Not applicable
Control of precursors and essential chemicals for the preparation of drugs: 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

Further information
Sources of key data used to: Internal technical data, data from raw material SDSs, OECD
SAFETY DATA SHEET

Fidaxomicin Solid Formulation

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
AR OEL: Argentina. Occupational Exposure Limits

AR OEL / CMP: TLV (Threshold Limit Value)

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AR / Z8