SAFETY DATA SHEET

Fidaxomicin Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Fidaxomicin Formulation

Manufacturer or supplier's details
Company : MSD
Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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 + P317 + P330 IF SWALLOWED: Get medical help.
Rinse mouth.
Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.
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Fidaxomicin Formulation

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fidaxomicin</td>
<td>873857-62-6</td>
<td>&gt;= 40 - &lt;= 60</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 15 - &lt;= 30</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 5 - &lt;= 15</td>
</tr>
</tbody>
</table>

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 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 : 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.

5. FIREFIGHTING 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

Specific extinguishing method : Use extinguishing measures that are appropriate to local cir-
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.
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.

7. HANDLING AND STORAGE

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.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parame-</th>
<th>Basis</th>
</tr>
</thead>
</table>

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SAFETY DATA SHEET

Fidaxomicin Formulation

<table>
<thead>
<tr>
<th>Substance</th>
<th>(Form of exposure)</th>
<th>TWA</th>
<th>Permissible concentration</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fidaxomicin</td>
<td>873857-62-6</td>
<td>200 µg/m³ (OEB 2)</td>
<td>Internal</td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
<td></td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
<td></td>
</tr>
</tbody>
</table>

**Engineering measures**: Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.

**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
- **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.

**Eye protection**: Wear the following personal protective equipment:

- Safety glasses

**Skin and body protection**: Skin should be washed after contact.

**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.

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
### SAFETY DATA SHEET

**Fidaxomicin Formulation**

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</tr>
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<tbody>
<tr>
<td>2.4</td>
<td>10.10.2020</td>
<td>1732341-00007</td>
<td>23.03.2020</td>
<td>05.06.2017</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not classified as a flammability hazard</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>log Pow: 4.4</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td></td>
</tr>
<tr>
<td>The substance or mixture is not classified as oxidizing.</td>
<td></td>
</tr>
<tr>
<td>Molecular weight</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

### 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.

### 11. TOXICOLOGICAL INFORMATION
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</tbody>
</table>

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

### Acute toxicity

Harmful if swallowed.

#### Product:
Acute oral toxicity:
- Acute toxicity estimate: 833.33 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

#### 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.

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

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.

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

### NOAEL
- **Species:** Dog
- **NOAEL:** 9,600 mg/kg
- **Application Route:** Oral
- **Exposure time:** 3 M
- **Symptoms:** Vomiting
- **Remarks:** No significant adverse effects were reported

### NOAEL
- **Species:** Monkey
- **NOAEL:** 90 mg/kg
- **Application Route:** Oral
- **Exposure time:** 28 D
- **Remarks:** No significant adverse effects were reported

### NOAEL
- **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

### Starch:
- **Species:** Rat
- **NOAEL:** >= 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
12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Fidaxomicin:
Toxicity to algae/aquatic plants
- EC50 (Anabaena flos-aquae (cyanobacterium)): > 18.4 mg/l
  Method: OECD Test Guideline 201
  Remarks: No toxicity at the limit of solubility
- NOEC (Anabaena flos-aquae (cyanobacterium)): 5.8 mg/l
  Method: OECD Test Guideline 201
  Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms
- EC50: > 50 mg/l
  Exposure time: 3 h
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209
- NOEC: 5.9 mg/l
  Exposure time: 3 h
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity)
- NOEC: 8.91 mg/l
  Exposure time: 32 d
  Species: Pimephales promelas (fathead minnow)
  Method: OECD Test Guideline 210
  Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
- NOEC: 19.6 mg/l
  Exposure time: 21 d
  Species: Daphnia magna (Water flea)
  Method: OECD Test Guideline 211

Cellulose:
Toxicity to fish
- LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
  Exposure time: 48 h
  Remarks: Based on data from similar materials

Persistence and degradability

Components:

Cellulose:
Biodegradability
- Result: Readily biodegradable.
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Fidaxomicin Formulation

Bioaccumulative potential

Components:

Fidaxomicin:
Partition coefficient: n-octanol/water : log Pow: 4.4

Mobility in soil

Components:

Fidaxomicin:
Distribution among environmental compartments : log Koc: 0.80

Other adverse effects
No data available

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.

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 IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
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IECSC : not determined

16. OTHER INFORMATION

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

All abbreviations are defined in the SDS.

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 use.
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.

IN / EN