SAFETY DATA SHEET

Fidaxomicin Formulation

SECTION 1. IDENTIFICATION

Product name : Fidaxomicin Formulation
Other means of identification : No data available

Manufacturer or supplier's details
Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
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 doctor if you feel unwell. Rinse mouth.

Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

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SAFETY DATA SHEET

Fidaxomicin Formulation

Substance / Mixture : Mixture

Components

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

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

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
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.
- 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:
- 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 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)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
Fidaxomicin Formulation

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS Number</th>
<th>TWA (Total dust)</th>
<th>CA AB OEL</th>
<th>TWA (respirable dust fraction)</th>
<th>CA BC OEL</th>
<th>TWAEV (total dust)</th>
<th>CA QC OEL</th>
<th>TWA</th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
<td>10 mg/m³</td>
<td>ACGIH</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 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES
- Appearance: solid
- Color: white to off-white
## Odor
: No data available

## Odor Threshold
: No data available

## pH
: Not applicable

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

Active ingredient

## Initial boiling point and boiling range
: Not applicable

## Flash point
: Not applicable

## Evaporation rate
: No data available

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

## Flammability (liquids)
: No data available

## Upper explosion limit / Upper flammability limit
: No data available

## Lower explosion limit / Lower flammability limit
: No data available

## Vapor pressure
: No data available

## Relative vapor density
: No data available

## Density
: No data available

## Solubility(ies)

- **Water solubility**
  : No data available

## Partition coefficient: n-octanol/water

- **log Pow**: 4.4

Active ingredient

## Autoignition temperature
: No data available

## Decomposition temperature
: No data available

## Viscosity

- **Viscosity, kinematic**
  : No data available

## Explosive properties
: Not explosive

## Oxidizing properties
: The substance or mixture is not classified as oxidizing.

## Molecular weight
: Not applicable

## Particle size
: No data available
SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

<table>
<thead>
<tr>
<th>Route</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin contact</td>
<td></td>
</tr>
<tr>
<td>Ingestion</td>
<td></td>
</tr>
<tr>
<td>Eye contact</td>
<td></td>
</tr>
</tbody>
</table>

Acute toxicity

Harmful if swallowed.

Product:

<table>
<thead>
<tr>
<th>Route</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 1,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50 (Dog): &gt; 120 mg/kg</td>
</tr>
<tr>
<td>Acute toxicity (other routes of administration)</td>
<td>LD50 (Rat): 200 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intravenous</td>
</tr>
</tbody>
</table>

Components:

Fidaxomicin:

<table>
<thead>
<tr>
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<th>Value</th>
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</thead>
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<tr>
<td>Acute oral toxicity</td>
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</tr>
<tr>
<td>Acute toxicity (other routes of administration)</td>
<td>LD50 (Rat): 200 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intravenous</td>
</tr>
</tbody>
</table>

Cellulose:

<table>
<thead>
<tr>
<th>Route</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): &gt; 5.8 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 4 h</td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rabbit): &gt; 2,000 mg/kg</td>
</tr>
</tbody>
</table>

Starch:

<table>
<thead>
<tr>
<th>Route</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rabbit): &gt; 2,000 mg/kg</td>
</tr>
</tbody>
</table>

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 sensitization

**Skin sensitization**
Not classified based on available information.

**Respiratory sensitization**
Not classified based on available information.

**Components:**

**Starch:**
Test Type: Maximization Test
Routes of exposure: 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
SAFETY DATA SHEET

Fidaxomicin Formulation

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 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
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

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

Starch:
Species: Rat
NOAEL: >= 2,000 mg/kg
Application Route: Skin contact
**SAFETY DATA SHEET**

**Fidaxomicin 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>3.7</td>
<td>04/04/2023</td>
<td>1732000-00012</td>
<td>10/01/2022</td>
<td>06/05/2017</td>
</tr>
</tbody>
</table>

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

**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  
Method: OECD Test Guideline 209

NOEC: 5.9 mg/l  
Exposure time: 3 h  
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
Persistence and degradability

Components:

Cellulose:
Biodegradability : Result: Readily biodegradable.

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

SECTION 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.

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

TDG
Not regulated as a dangerous good
SAFETY DATA SHEET

Fidaxomicin Formulation

Version 3.7
Revision Date: 04/04/2023
SDS Number: 1732000-00012
Date of last issue: 10/01/2022
Date of first issue: 06/05/2017

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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)
CA BC OEL : Canada. British Columbia OEL
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA : 8-hour, time-weighted average
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average
CA QC OEL / TWAEV : Time-weighted average exposure value

All other abbreviations are as follows:
ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH - American Conference of Governmental Industrial Hygienists; 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SAFETY DATA SHEET

Fidaxomicin Formulation

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