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 : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

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

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 POISON CENTER/doctor if you feel unwell. Rinse mouth.

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

Other hazards
None known.

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 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 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
SAFETY DATA SHEET

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Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions:
- Discharge into the environment must be avoided.
- 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.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- 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 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEB (to-10 mg/m³</td>
<td>CA QC OEL</td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Fidaxomicin Formulation

<table>
<thead>
<tr>
<th>Dimension</th>
<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></td>
<td>3.0</td>
<td>09/13/2019</td>
<td>1732000-00005</td>
<td>04/24/2019</td>
<td>06/05/2017</td>
</tr>
</tbody>
</table>

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

**Personal protective equipment**

<table>
<thead>
<tr>
<th>Respiratory protection</th>
<th>Filter type</th>
<th>Hand protection</th>
<th>Material</th>
<th>Remarks</th>
<th>Eye protection</th>
<th>Skin and body protection</th>
<th>Hygiene measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.</td>
<td>Particulates type</td>
<td>Chemical-resistant gloves</td>
<td>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.</td>
<td></td>
<td>Wear the following personal protective equipment: Safety glasses</td>
<td>Skin should be washed after contact.</td>
<td></td>
</tr>
</tbody>
</table>

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

<table>
<thead>
<tr>
<th>Appearance</th>
<th>Color</th>
<th>Odor</th>
<th>Odor Threshold</th>
<th>pH</th>
<th>Melting point/freezing point</th>
</tr>
</thead>
<tbody>
<tr>
<td>solid</td>
<td>white to off-white</td>
<td>No data available</td>
<td>No data available</td>
<td>Not applicable</td>
<td>175 - 185 °C</td>
</tr>
</tbody>
</table>

**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
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: No hazardous decomposition products are known.
SECTION 11. TOXICOLOGICAL INFORMATION

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

Starch:
Acute oral toxicity : LD50 (Mouse): > 5,000 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Serious eye damage/eye irritation
Not classified based on available information.

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.
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

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  
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  
Species: Rat  
Application Route: Intravenous injection  
Developmental Toxicity: NOAEL: 7 mg/kg body weight  
Remarks: No significant adverse effects were reported

Effects on fetal development  
Species: Rat  
Application Route: Intravenous injection  
Developmental Toxicity: NOAEL: 7 mg/kg body weight  
Remarks: No significant adverse effects were reported

STOT-single exposure  
Not classified based on available information.

STOT-repeated exposure  
Not classified based on available information.

Repeated dose toxicity

Components:

<table>
<thead>
<tr>
<th>Fidaxomicin:</th>
</tr>
</thead>
</table>
| 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

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
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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:
- 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.
- 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
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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

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

AICS - Australian Inventory of Chemical Substances; 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; KECI - 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, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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


Revision Date: 09/13/2019

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

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.

CA / Z8