SECTION 1. IDENTIFICATION

Product name : Fidaxomicin Formulation

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 OSHA Hazard Communication Standard (29 CFR 1910.1200)
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

Substance / Mixture : Mixture
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

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>
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<tbody>
<tr>
<td>Fidaxomicin</td>
<td>873857-62-6</td>
<td>TWA</td>
<td>200 µg/m³ (OEB 2)</td>
<td>Internal</td>
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<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td>TWA (total) mg/m³</td>
<td>TWA (total dust) mg/m³</td>
<td>TWA (respirable fraction) mg/m³</td>
<td></td>
</tr>
<tr>
<td>------------------</td>
<td>-------------------</td>
<td>------------------------</td>
<td>-------------------------------</td>
<td></td>
</tr>
<tr>
<td>Starch 9005-25-8</td>
<td>10 mg/m³</td>
<td>15 mg/m³</td>
<td>5 mg/m³</td>
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</tr>
<tr>
<td></td>
<td>NIOSH REL</td>
<td>OSHA Z-1</td>
<td>OSHA Z-1</td>
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</tr>
</tbody>
</table>

**Engineering measures**

Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.

**Personal protective equipment**

**Respiratory protection**

General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**Hand protection**

Material: 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.
**Fidaxomicin Formulation**

**Appearance**: solid

**Color**: white to off-white

**Odor**: No data available

**Odor Threshold**: No data available

**pH**: Not applicable

**Melting point/freezing point**: 347 - 365 °F / 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.
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 products: 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
Acute inhalation toxicity: LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Starch:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Fidaxomicin Formulation

<table>
<thead>
<tr>
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<th>SDS Number: 1731985-00012</th>
<th>Date of last issue: 04/04/2023</th>
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</tr>
</thead>
</table>

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 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
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Fidaxomicin Formulation

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<tr>
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</tr>
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<tbody>
<tr>
<td>3.9</td>
<td>09/30/2023</td>
<td>1731985-00012</td>
<td>04/04/2023</td>
<td>06/05/2017</td>
</tr>
</tbody>
</table>

**Cellulose:**

Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES) Result: negative

Genotoxicity in vivo: Test Type: In vitro mammalian cell gene mutation test 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

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**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
Fidaxomicin Formulation

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

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
Fidaxomicin Formulation

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

SECTION 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 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

Persistence and degradability

Cellulose:
Biodegradability: Result: Readily biodegradable.

Bioaccumulative potential

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

Mobility in soil

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

49 CFR
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards: Acute toxicity (any route of exposure)

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

Fidaxomicin 873857-62-6
Cellulose 9004-34-6
Starch 9005-25-8

California Permissible Exposure Limits for Chemical Contaminants

Cellulose 9004-34-6
Starch 9005-25-8

The ingredients of this product are reported in the following inventories:

AICS: not determined
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

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DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

HMIS® IV:

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA : 8-hour, time-weighted average
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA : 8-hour time weighted average

AIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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
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Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 09/30/2023

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.

US / Z8