SAFETY DATA SHEET

Fidaxomicin Solid Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Fidaxomicin Solid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : MSD
              117 16th Road
              1685 Halfway house, Midrand, South Africa
   Telephone : +27 11 655 3000
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   +1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Acute toxicity, Category 4
   H302: Harmful if swallowed.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   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.

Hazardous components which must be listed on the label:
Fidaxomicin Solid Formulation

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. 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

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fidaxomicin</td>
<td>873857-62-6</td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 4; H302</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td>532-32-1</td>
<td>208-534-8</td>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed
Risks: 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.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.
Hazardous combustion products: Carbon oxides
Metal oxides
Chlorine compounds

5.3 Advice for firefighters
Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

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 contami-
nated 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types: Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</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 OEL-RL (Respirable dust)</td>
<td>5 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Recommended Limit</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA OEL-RL (inhalable dust)</td>
<td>10 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Recommended Limit</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL OEL-RL (Dust)</td>
<td>20 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Recommended Limit</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium benzoate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>0,1 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>62,5 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>1,5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>0,06 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>31,25 mg/kg bw/day</td>
</tr>
</tbody>
</table>
Consumers Ingestion Long-term systemic effects 16.6 mg/kg bw/day

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citric acid</td>
<td>Fresh water</td>
<td>0.44 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.044 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>34.6 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>3.46 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>33.1 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Sodium citrate</td>
<td>Fresh water</td>
<td>0.44 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.044 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>34.6 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>3.46 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>31.1 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td>Fresh water</td>
<td>0.13 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>0.305 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.013 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>10 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>1.76 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.176 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.276 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Oral (Secondary Poisoning)</td>
<td>300 mg/kg food</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

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

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.

Hand protection
Material: Chemical-resistant gloves

Skin and body protection: Work uniform or laboratory coat.
Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the rec-
ommended guidelines, use respiratory protection.

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- **Appearance**: granules
- **Colour**: White to light yellow
- **Odour**: No data available
- **Odour 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.
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapour pressure**: Not applicable
- **Relative vapour density**: Not applicable
- **Relative density**: No data available
- **Density**: No data available
- **Solubility(ies)**
  - **Water solubility**: No data available
- **Partition coefficient: n-octanol/water**: Not applicable
- **Auto-ignition 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.

9.2 Other information
SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
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): LD50 (Rat): 200 mg/kg
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<table>
<thead>
<tr>
<th>Component</th>
<th>Application Route: Intravenous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium benzoate:</td>
<td></td>
</tr>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 2.000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Assessment: The substance or mixture has no acute oral toxicity</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rabbit): &gt; 2.000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Citric acid:</td>
<td></td>
</tr>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Mouse): 5.400 mg/kg</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): &gt; 2.000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 402</td>
</tr>
<tr>
<td></td>
<td>Assessment: The substance or mixture has no acute dermal toxicity</td>
</tr>
</tbody>
</table>

**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
- Method: OECD Test Guideline 405
- Result: Irritation to eyes, reversing within 21 days

**Citric acid:**
- Species: Rabbit
- Method: OECD Test Guideline 405
- Result: Irritation to eyes, reversing within 21 days
Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Sodium benzoate:

Test Type: Local lymph node assay (LLNA)
Exposure routes: 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

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:

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
  Remarks: No significant adverse effects were reported
- 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

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 foetal development:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
</tbody>
</table>

Citric acid:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>One-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
</tbody>
</table>

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Fidaxomicin:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>90 mg/kg</td>
<td>Oral</td>
<td>28 D</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td>Rat</td>
<td>62.5 mg/kg</td>
<td>Intravenous</td>
<td>14 D</td>
<td></td>
</tr>
<tr>
<td>Dog</td>
<td>9.600 mg/kg</td>
<td>Oral</td>
<td>3 M</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td>Monkey</td>
<td>90 mg/kg</td>
<td>Oral</td>
<td>28 D</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td>Juvenile rat</td>
<td>200 mg/kg</td>
<td>Oral</td>
<td>28 D</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>
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Fidaxomicin Solid Formulation

Version: 1.3
Revision Date: 09.04.2021
SDS Number: 4750803-00004
Date of last issue: 10.10.2020
Date of first issue: 15.08.2019

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

12.1 Toxicity

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 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

**Sodium benzoate:**

Toxicity to fish: \( \text{LC}_{50} \) (Pimephales promelas (fathead minnow)): 484 mg/l
- Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: \( \text{EC}_{50} \) (Daphnia magna (Water flea)): > 100 mg/l
- Exposure time: 96 h

Toxicity to algae/aquatic plants: \( \text{EC}_{50} \) (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

\( \text{NOEC} \) (Pseudokirchneriella subcapitata (green algae)): 32 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

**Citric acid:**

Toxicity to fish: \( \text{LC}_{50} \) (Pimephales promelas (fathead minnow)): > 100 mg/l
- Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: \( \text{EC}_{50} \) (Daphnia magna (Water flea)): 1.535 mg/l
- Exposure time: 24 h

### 12.2 Persistence and degradability

**Components:**

**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

### 12.3 Bioaccumulative potential

**Components:**

**Fidaxomicin:**

Partition coefficient: \( n- \log \text{Pow} \): 4.4
octanol/water

**Sodium benzoate:**
Partition coefficient: n-octanol/water
: log Pow: 1.88

**Citric acid:**
Partition coefficient: n-octanol/water
: log Pow: -1.72

### 12.4 Mobility in soil

**Components:**

**Fidaxomicin:**
Distribution among environmental compartments
: log Koc: 0.80

### 12.5 Results of PBT and vPvB assessment

**Product:**
Assessment
: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Other adverse effects

**Product:**
Endocrine disrupting potential
: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

**Product**
: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

**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

#### 14.1 UN number

Not regulated as a dangerous good

#### 14.2 UN proper shipping name

Not regulated as a dangerous good
SAFETY DATA SHEET

Fidaxomicin Solid Formulation

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14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 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
IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements
H302: Harmful if swallowed.
H319: Causes serious eye irritation.

Full text of other abbreviations
Acute Tox.: Acute toxicity
Eye Irrit.: Eye irritation
ZA OEL: South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL: Long term occupational exposure limits - recommended limit
ZA OEL / STEL OEL-RL: Short term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada);
Further information


Classification of the mixture:

Acute Tox. 4   H302

Classification procedure:

Calculation method

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.

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