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
   Kilsheelan
   Clonmel Tipperary, IE
   Telephone : 353-51-601000
   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.
Fidaxomicin Solid Formulation

Hazardous components which must be listed on the label:
Fidaxomicin

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.

Ecological information: 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.

Toxicological information: 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.

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>Components</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>838-62-6</td>
<td>176-62-6</td>
<td>176-62-6</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>208-534-8</td>
<td>208-534-8</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 method: Use extinguishing measures that are appropriate to local cir-
SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006

Fidaxomicin Solid Formulation

Version 1.3
Revision Date: 09.04.2021
SDS Number: 4757503-00004
Date of last issue: 10.10.2020
Date of first issue: 15.08.2019

ods 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 contaminated 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

Occupational Exposure Limits

<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>
</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</td>
<td>1,5 mg/m3</td>
</tr>
</tbody>
</table>
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Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<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.
SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006

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SDS Number: 4757503-00004
Date of last issue: 10.10.2020
Date of first issue: 15.08.2019

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 recommended guidelines, use respiratory protection. Equipment should conform to NS EN 143

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: granules
Colour: White to light yellow
Odour: No data available
Odour Threshold: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Flash point: Not applicable
Auto-ignition temperature: No data available
Decomposition temperature Decomposition temperature: No data available
pH: No data available
Viscosity Viscosity, kinematic: Not applicable
Solubility(ies) Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Vapour pressure: Not applicable
Relative density: No data available
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Density : No data available
Relative vapour density : Not applicable
Particle characteristics
  Particle size : No data available

9.2 Other information
Explosives : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Evaporation rate : Not applicable
Molecular weight : No data available

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 hazard classes as defined in Regulation (EC) No 1272/2008
Information on likely routes of exposure : Inhalation
  Skin contact
  Ingestion
  Eye contact

Acute toxicity
Harmful if swallowed.
Fidaxomicin Solid Formulation

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 administration) : LD50 (Rat): 200 mg/kg
Application Route: Intravenous

Sodium benzoate:
Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
Assessment: The substance or mixture has no acute oral toxicity
Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg
Remarks: Based on data from similar materials

Citric acid:
Acute oral toxicity : LD50 (Mouse): 5.400 mg/kg
Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

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
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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

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
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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 : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

Citric acid:  
Effects on foetal development : Test Type: One-generation reproduction toxicity study  
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

Species : Juvenile rat
NOAEL : 200 mg/kg
Application Route : Oral
Exposure time : 28 D
Remarks : No significant adverse effects were reported

Species : Rat
NOAEL : 1,000 mg/kg
Application Route : Ingestion
Exposure time : 24 Months

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.

### 11.2 Information on other hazards

**Endocrine disrupting properties**

**Product:**

**Assessment** : 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.

**Experience with human exposure**

**Components:**

**Fidaxomycin:**

**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

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

Sodium benzoate:

Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 484 mg/l
   Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
   Exposure time: 96 h

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
   Exposure time: 72 h
   Method: OECD Test Guideline 201

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

**Citric acid:**
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (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-octanol/water: log Pow: 4,4

**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 or ID number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

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 Maritime transport in bulk according to IMO instruments
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
REACH - Restrictions on the manufacture, placing on market: Not applicable
the market and use of certain dangerous substances, preparations and articles (Annex XVII)
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).
REACH - List of substances subject to authorisation (Annex XIV)
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals
Not applicable

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

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); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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
## Fidaxomicin Solid Formulation

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Further information


Classification of the mixture: Acute Tox. 4 H302

Classification procedure: Calculation method

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