

against

Fidaxomicin Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
|---------|----------------|---------------|---------------------------------|
| 2.12 | 28.09.2024 | 1732338-00015 | Date of first issue: 05.06.2017 |

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

| 1.1 | Product identifier Trade name | : | Fidaxomicin Formulation |
|-----|--|-----------|--|
| 1.2 | Relevant identified uses of th Use of the Sub- stance/Mixture | | ubstance or mixture and uses advised Pharmaceutical |
| | Recommended restrictions on use | : | Not applicable |
| 1.3 | Details of the supplier of the s Company | safo : | ety data sheet 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. |



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|-----------------|---------------------------|--|--|--|--|--|
| | | 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

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|---------------|---|--------------------|--------------------------|
| Fidaxomicin | 873857-62-6 | Acute Tox. 4; H302 | >= 40 - <= 60 |

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 ad- vice 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). |

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

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| 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 | | : | | vater as a precaution. htion if irritation develops and persists. | | |
| If swallowed | | : | so by medical pe Get medical atter Rinse mouth thor | | | |
| I.2 Most ir Risks | mportant symptoms ar | nd e | ffects, both acut Harmful if swallov | - | | |
| | | • | | | | |
| 1.3 Indicat . Treatr | • | mec | | d special treatment needed ically and supportively. | | |
| | | - | | | | |
| - | uishing media le extinguishing media | : | Water spray Alcohol-resistant Carbon dioxide (Dry chemical | | | |
| Unsuit media | table extinguishing | : | None known. | | | |
| 5.2 Specia | I hazards arising from | the | substance or mi | xture | | |
| Specif fightin | ic hazards during fire- g | : | Exposure to com | bustion products may be a hazard to health. | | |
| Hazar ucts | dous combustion prod- | : | Carbon oxides | | | |
| 5.3 Advice | o for firefighters | | | | | |
| Specia | al protective equipment | : | | e, wear self-contained breathing apparatus. tective equipment. | | |
| Specif ods | ic extinguishing meth- | : | cumstances and Use water spray | g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to d | | |



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| | | Evacuate area | a. |
| SECTION | N 6: Accidental relea | ise measures | |
| 6.1 Perso | nal precautions, prote | ective equipment a | nd emergency procedures |
| Perso | onal precautions | Follow safe ha | protective equipment. andling advice (see section 7) and personal pro- nent recommendations (see section 8). |
| 6.2 Enviro | onmental precautions | | |
| Envir | onmental precautions | Prevent furthe Retain and di | to the environment. er leakage or spillage if safe to do so. spose of contaminated wash water. ies should be advised if significant spillages ntained. |
| 6.3 Metho | ods and material for co | ontainment and cle | aning up |
| Meth | ods for cleaning up | tainer for disp Local or natio posal of this n employed in t mine which re Sections 13 a | vacuum up spillage and collect in suitable con- osal. nal regulations may apply to releases and dis- naterial, as well as those materials and items he cleanup of releases. You will need to deter- gulations are applicable. nd 15 of this SDS provide information regarding 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 | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
|--|---|--|
| Local/Total ventilation Advice on safe handling | | Use only with adequate ventilation. 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 as- sessment |
| Hygiene measures | : | Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment. 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. |



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| 7.2 Condi | itions for safe storage | , including a | any incompatibilities |
| | irements for storage and containers | | in properly labelled containers. Store in accordance with articular national regulations. |
| Advice on common storage : | | | t store with the following product types: g 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

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|-------------|-----------------|-------------------------------|--------------------|----------|
| Fidaxomicin | 873857-62- 6 | TWA | 200 µg/m3 (OEB 2) | Internal |

8.2 Exposure controls

Engineering measures

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

| Personal protective equipment | | | | | |
|--|---|--|--|--|--|
| Eye/face protection | : | Wear the following personal protective equipment: Safety glasses Equipment should conform to NS EN 166 | | | |
| Hand protection | | | | | |
| Material | : | Chemical-resistant gloves | | | |
| Remarks | : | Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub- stance and 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. | | | |
| Skin and body protection Respiratory protection | : | Skin should be washed after contact. If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to NS EN 143 | | | |
| Filter type | : | Particulates type (P) | | | |

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| Physical state | : | solid |
|---|---|--|
| Colour | : | white to off-white |
| Odour | : | No data available |
| Odour Threshold | : | No data available |
| Melting point/freezing point | : | 175 - 185 °C Active ingredient |
| Initial boiling point and boiling range | : | Not applicable |
| 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 |
| Flash point | : | Not applicable |
| | | |
| Auto-ignition temperature | : | No data available |
| Auto-ignition temperature Decomposition temperature | | |
| | | |
| Decomposition temperature | : | No data available Not applicable |
| Decomposition temperature pH Viscosity | : | No data available Not applicable |
| Decomposition temperature pH Viscosity Viscosity, kinematic Solubility(ies) | : | No data available Not applicable No data available |
| Decomposition temperature pH Viscosity Viscosity, kinematic Solubility(ies) Water solubility Partition coefficient: n- | : | No data available Not applicable No data available No data available log Pow: 4,4 |
| Decomposition temperature pH Viscosity Viscosity, kinematic Solubility(ies) Water solubility Partition coefficient: n- octanol/water | : | No data available Not applicable No data available No data available log Pow: 4,4 Active ingredient |

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|-----------------|-------------------------------------|-----|----------------------|---|
| | cle characteristics article size | : N | lo data available | 9 |
| • • •• | information osives | : N | lot explosive | |
| Oxidi | zing properties | : Т | he substance o | r mixture is not classified as oxidizing. |
| Evap | oration rate | : N | lo data available | 9 |
| Mole | cular weight | : N | lot applicable | |
| | | | | |

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 : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

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 | : | Skin contact Ingestion Eye contact | J | |
|--|---|--|---|-----|
| Acute toxicity Harmful if swallowed. | | | | |
| Product: | | | | |
| Acute oral toxicity | : | Acute toxicity Method: Calcu | | /kg |

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|------------|---|------|---|---|
| Compo | onents: | | | |
| Fidaxo | micin: | | | |
| Acute of | oral toxicity | : | LD50 (Rat): > 1.00 | 00 mg/kg |
| | | | LD50 (Dog): > 120 |) mg/kg |
| | oxicity (other routes of stration) | : | LD50 (Rat): 200 n Application Route | |
| Skin co | orrosion/irritation | | | |
| Not cla | ssified based on availa | ble | information. | |
| | s eye damage/eye irri | | | |
| | ssified based on availa | | | |
| Respir | atory or skin sensitis | atio | n | |
| | ensitisation ssified based on availa | ble | information. | |
| Respir | atory sensitisation | | | |
| Not cla | ssified based on availa | ble | information. | |
| | cell mutagenicity ssified based on availa | ble | information. | |
| Compo | onents: | | | |
| Fidaxo | micin: | | | |
| | oxicity in vitro | : | Test Type: Bacter Result: negative | ial reverse mutation assay (AMES) |
| | | | | osome aberration test in vitro lese hamster ovary cells |
| Genoto | oxicity in vivo | : | Test Type: Mamm cytogenetic assay Species: Rat Application Route Result: negative | |
| | | | Test Type: comet Species: Rat Result: negative | assay |

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.



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| <u>Com</u> | ponents: | | |
| Fidax | komicin: | | |
| Effec | ts on fertility | Species: Rat Application Rout | lity/early embryonic development te: Intravenous injection : 6,3 mg/kg body weight |
| Effec ment | ts on foetal develop- | Species: Rat Application Rout Developmental | ryo-foetal development te: Intravenous injection Toxicity: NOAEL: 12,6 mg/kg body weight gnificant adverse effects were reported |
| | | Species: Rabbit Application Rou Developmental | ryo-foetal development te: Intravenous injection Toxicity: NOAEL: 7 mg/kg body weight gnificant 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:

| Fidaxomicin:Species:NOAEL:Application Route:Exposure time:Remarks: | Rat 90 mg/kg Oral 28 D No significant adverse effects were reported |
|--|---|
| Species:NOAEL:Application Route:Exposure time: | Rat 62,5 mg/kg Intravenous 14 D |
| Species:NOAEL:Application Route:Exposure time:Symptoms:Remarks: | Dog 9.600 mg/kg Oral 3 M Vomiting No significant adverse effects were reported |
| Species:NOAEL:Application Route:Exposure time: | Monkey 90 mg/kg Oral 28 D |



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|------------------------|--|--------|---|--|--|--|--|--|--|
| Rema | Remarks Species NOAEL Application Route Exposure time Remarks | | : No significant adverse effects were reported | | | | | | |
| NOAI Applie Expo | | | Juvenile rat 200 mg/kg Oral 28 D No significant adverse effects were reported | | | | | | |
| - | ration toxicity lassified based on ava | ilahle | information | | | | | | |
| | mation on other haza | | information. | | | | | | |
| Endo | crine disrupting prop | pertie | S | | | | | | |
| Prod | uct: | | | | | | | | |
| Asse | Assessment | | The substance/mixture does not contain components consid- ered 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. | | | | | | |
| Expe | rience with human ex | xposı | ire | | | | | | |
| <u>Com</u> | ponents: | | | | | | | | |
| Fida> Inges | tion | : | Symptoms: Abo | dominal pain, Nausea, Vomiting, constipation | | | | | |
| ECTION | 12: Ecological inf | orma | tion | | | | | | |
| 2.1 Toxic | sitv | | | | | | | | |
| - | ponents: | | | | | | | | |
| | comicin: | | | | | | | | |
| | ity to algae/aquatic | : | Exposure time: Method: OECD | na flos-aquae (cyanobacterium)): > 18,4 mg/l 72 h Test Guideline 201 oxicity at the limit of solubility | | | | | |
| | | | Exposure time: Method: OECD | ena flos-aquae (cyanobacterium)): 5,8 mg/l 72 h Test Guideline 201 oxicity at the limit of solubility | | | | | |
| Toxic | ity to microorganisms | : | | | | | | | |

Method: OECD Test Guideline 209

NOEC : 5,9 mg/l

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| | | Exposure time: 3 Test Type: Respir Method: OECD T | ration inhibition |
| y to fish (Chronic tox- | : | Method: OECD T | ales promelas (fathead minnow) |
| c invertebrates (Chron- | : | NOEC: 19,6 mg/l Exposure time: 2 ⁻¹ Species: Daphnia Method: OECD To | magna (Water flea) |
| - | ity | | |
| cumulative potential | | | |
| onents: | | | |
| on coefficient: n- | : | log Pow: 4,4 | |
| ity in soil | | | |
| onents: | | | |
| ution among environ- | : | log Koc: 0,80 | |
| ts of PBT and vPvB as | se | ssment | |
| <u>ct:</u> | | | |
| sment | : | to be either persis | ixture contains no components considered stent, bioaccumulative and toxic (PBT), or ind very bioaccumulative (vPvB) at levels of |
| crine disrupting prope | rtie | S | |
| <u>ct:</u> | | | |
| sment | : | ered to have endo REACH Article 57 | ixture does not contain components consid- ocrine disrupting properties according to 7(f) or Commission Delegated regulation or Commission Regulation (EU) 2018/605 at higher. |
| | c invertebrates (Chron- city) stence and degradabili ta available cumulative potential onents: omicin: on coefficient: n- ol/water ity in soil onents: omicin: oution among environ- l compartments ts of PBT and vPvB as oct: sment | ty to daphnia and other : c invertebrates (Chron- city) stence and degradability ta available cumulative potential conents: omicin: on coefficient: n- : ol/water ity in soil conents: omicin: ution among environ- : l compartments ts of PBT and vPvB asses ts of PBT and vPvB asses ts of PBT and vPvB asses ts of PBT and vPvB asses | Test Type: Respin Method: OECD T NOEC: 8,91 mg/l Exposure time: 32 Species: Pimepha Method: OECD T Remarks: No toxi NOEC: 19,6 mg/l Exposure time: 2' Species: Daphnia Method: OECD T Exposure time: 2' Species: Daphnia Method: OECD T stence and degradability ta available cumulative potential onents: omicin: on coefficient: n- ol/water ity in soil onents: omicin: ution among environ- l compartments ts of PBT and vPvB assessment tet: sment : This substance/m to be either persis very persistent ar 0.1% or higher. |

No data available



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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. Do not dispose of waste into sewer. |
| Contaminated packaging | Empty containers should be taken to an approved waste han- dling 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

| ADN | : | Not regulated as a dangerous good |
|---------------------------------|---|-----------------------------------|
| ADR | : | Not regulated as a dangerous good |
| RID | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| ΙΑΤΑ | : | Not regulated as a dangerous good |
| 14.2 UN proper shipping name | | |
| ADN | : | Not regulated as a dangerous good |
| ADR | : | Not regulated as a dangerous good |
| RID | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| ΙΑΤΑ | : | Not regulated as a dangerous good |
| 14.3 Transport hazard class(es) | | |
| ADN | : | Not regulated as a dangerous good |
| ADR | : | Not regulated as a dangerous good |
| RID | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| ΙΑΤΑ | : | Not regulated as a dangerous good |
| 14.4 Packing group | | |
| ADN | : | Not regulated as a dangerous good |
| ADR | : | Not regulated as a dangerous good |
| RID | : | Not regulated as a dangerous good |
| | | |

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| IMDG | | : Not regulated a | s a dangerous good | |
| IATA | (Cargo) | : Not regulated as | s a dangerous good | |
| IATA | (Passenger) | : Not regulated as a dangerous good | | |
| 14.5 Envir | onmental hazards | | | |
| Not regulated as a dangerous good | | | | |
| - | al precautions for use | er | | |
| 4 4 7 Man:4 | me trenenent in bulls | | - 1 | |

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 the market and use of certain dangerous substances, mixtures and articles (Annex XVII) | : | Not applicable | |
|---|---|----------------|--|
| REACH - Candidate List of Substances of Very High | : | Not applicable | |
| Concern for Authorisation (Article 59). REACH - List of substances subject to authorisation | | Not applicable | |
| (Annex XIV) | • | | |
| Regulation (EC) on substances that deplete the ozone | : | Not applicable | |
| layer | | | |
| Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast) | : | Not applicable | |
| Regulation (EU) No 649/2012 of the European Parlia- | : | Not applicable | |
| ment and the Council concerning the export and import | | | |
| of dangerous chemicals | | | |
| Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. 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.



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Full text of H-Statements

H302 : Harmful if swallowed.

Full text of other abbreviations

Acute Tox. : Acute toxicity

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - 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 - 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; 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

Further information

| Sources of key data used to | : | Internal technical data, data from raw material SDSs, OECD |
|-----------------------------|---|--|
| compile the Safety Data | | eChem Portal search results and European Chemicals Agen- |
| Sheet | | cy, http://echa.europa.eu/ |

H302

Classification of the mixture:

Acute Tox. 4

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



Fidaxomicin Formulation

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