

Fidaxomicin Solid Formulation

| 2.2 30.09.2023 4750798-00008 Date of first issue: 15.08.2019 | Version 2.2 | Revision Date: 30.09.2023 | SDS Number: 4750798-00008 | Date of last issue: 04.04.2023 Date of first issue: 15.08.2019 | |
|--|----------------|---------------------------|------------------------------|---|--|
|--|----------------|---------------------------|------------------------------|---|--|

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

| Product name | : | Fidaxomicin Solid Formulation |
|----------------------------|------|---------------------------------|
| Manufacturer or supplier's | deta | nils |
| Company name of supplier | : | MSD |
| 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@msd.com |
| Recommended use of the c | hen | nical and restrictions on use |
| Recommended use | : | Pharmaceutical |

: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

Restrictions on use

| GHS Classification Acute toxicity (Oral) | : | Category 4 |
|--|---|---|
| GHS label elements Hazard pictograms | : | |
| Signal Word | : | Warning |
| Hazard Statements | : | H302 Harmful if swallowed. |
| Precautionary Statements | : | Prevention: P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. |
| | | Response: P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth. |
| | | Disposal: P501 Dispose of contents/ container to an approved waste disposal plant. |

Other hazards

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

Substance / Mixture : Mixture



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|-------------|--|---|--|--|
| Comp | oonents | | | |
| Cherr | nical name | | CAS-No. | Concentration (% w/w) |
| Fidax | omicin | | 873857-62-6 | >= 50 -< 70 |
| Cellul | ose | | 9004-34-6 | >= 20 -< 30 |
| Sodiu | m benzoate | | 532-32-1 | >= 1 -< 5 |
| Citric | acid | | 77-92-9 | >= 1 -< 5 |
| ECTION | 4. FIRST AID MEASU | | | |
| | ral advice | : In the case of advice immed | liately. | eel unwell, seek medical cases of doubt seek medica |
| lf inha | aled | | nove to fresh air. attention if symptom | s occur. |
| In cas | se of skin contact | : Wash with wa | | |
| In cas | se of eye contact | | se well with water. | levelops and persists. |
| lf swa | llowed | so by medica Get medical a Rinse mouth | l personnel. httention. thoroughly with wate | niting unless directed to do er. an unconscious person. |
| | important symptoms ffects, both acute and ed | : Harmful if swa Contact with o the skin. | allowed. dust can cause mec | hanical irritation or drying of ad to mechanical irritation. |
| Prote | ction of first-aiders | : First Aid resp and use the re when the pote | onders should pay a ecommended perso ential for exposure e | attention to self-protection, nal protective equipment exists (see section 8). |
| Notes | s to physician | | matically and suppo | |

| Suitable extinguishing media Unsuitable extinguishing media | | Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical None known. |
|---|---|---|
| Specific hazards during fire | : | Exposure to combustion products may be a hazard to health. |
| Hazardous combustion prod- ucts | : | Carbon oxides Metal oxides Chlorine compounds |
| Specific extinguishing meth- ods | : | Use extinguishing measures that are appropriate to local cir- cumstances 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. |



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| | ial protective equipment e-fighters | : | | e, wear self-contained breathing apparatus. tective equipment. |
| SECTION | 6. ACCIDENTAL RELE | AS | E MEASURES | |
| tive e | onal precautions, protec- equipment and emer- y procedures | : | Follow safe hand | tective equipment. ling advice (see section 7) and personal nent recommendations (see section 8). |
| Envir | onmental precautions | : | Retain and dispo | eakage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages |
| Methods and materials for containment and cleaning up | | : | container for disp Avoid dispersal of with compressed Dust deposits sh surfaces, as thes released into the Local or national disposal of this m employed in the determine which Sections 13 and | f dust in the air (i.e., clearing dust surfaces |

SECTION 7. HANDLING AND STORAGE

| 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 Advice on safe handling | | Use only with adequate ventilation. 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. |



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| | tions for safe storage | Wash contamina The effective op engineering con appropriate dego industrial hygien use of administra : Keep in properly Store in accorda | not eat, drink or smoke. ated clothing before re-use. eration of a facility should include review of trols, proper personal protective equipment, owning and decontamination procedures, ie monitoring, medical surveillance and the ative controls. v labeled containers. ince with the particular national regulations. in the following product types: |
| Materi | | Strong oxidizing | |

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

| | | P | | |
|-----------------|-------------|---|--|-----------------------|
| Components | CAS-No. | Value type (Form of exposure) | Control parame- ters / Permissible concentration | Basis |
| Fidaxomicin | 873857-62-6 | TWA | 200 µg/m3 (OEB 2) | Internal |
| Cellulose | 9004-34-6 | VLE-PPT | 10 mg/m³ | NOM-010- STPS-2014 |
| | | TWA | 10 mg/m ³ | ACGIH |
| Sodium benzoate | 532-32-1 | TWA (Inhalable particulate matter) | 2.5 mg/m ³ | ACGIH |

Ingredients with workplace control parameters

| 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 equipm | ent | |
| Respiratory protection | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. |
| Filter type Hand protection | : | Particulates type |
| Material | : | Chemical-resistant gloves |
| 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. |
| Skin and body protection | : | Work uniform or laboratory coat. |

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance



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| | | | | | |
| | Color | | : | White to light yell | ow |
| | Odor | | : | No data available | |
| | Odor Tł | nreshold | : | No data available | |
| | рН | | : | No data available | |
| | Melting | point/freezing point | : | No data available | |
| | Initial bo range | oiling point and boiling | : | No data available | |
| | Flash p | oint | : | Not applicable | |
| | Evapora | ation rate | : | Not applicable | |
| | Flamma | ability (solid, gas) | : | May form explosi handling or other | ve dust-air mixture during processing, means. |
| | Flamma | ability (liquids) | : | No data available | |
| | | explosion limit / Upper bility limit | : | No data available | |
| | | explosion limit / Lower bility limit | : | No data available | |
| | Vapor p | pressure | : | Not applicable | |
| | Relative | e vapor density | : | Not applicable | |
| | Relative | e density | : | No data available | • |
| | Density | | : | No data available | • |
| | Solubili Wate | ty(ies) er solubility | : | No data available | |
| | Partition octanol | n coefficient: n- | : | Not applicable | |
| | | ition temperature | : | No data available | • |
| | Decom | position temperature | : | No data available | |
| | Viscosit Visc | ty osity, kinematic | : | Not applicable | |
| | Explosi | ve properties | : | Not explosive | |
| | Oxidizir | ng properties | : | The substance or | mixture is not classified as oxidizing. |
| | Molecu | lar weight | : | No data available | |



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| Partic | le size | : No data available | | | | | |
| SECTION | 10. STABILITY AND RE | EAC | ΤΙVITY | | | | |
| Chem | Reactivity Chemical stability Possibility of hazardous reac- tions | | Stable under no May form explo handling or othe | s a reactivity hazard. rmal conditions. sive dust-air mixture during processing, er means. strong oxidizing agents. | | | |
| | tions to avoid | : | Heat, flames an Avoid dust form | ation. | | | |
| | patible materials dous decomposition cts | : | Oxidizing agent No hazardous c | s lecomposition products are known. | | | |
| SECTION | 11. TOXICOLOGICAL I | NFC | RIVIATION | | | | |
| Inhala Skin c Ingest | contact | | | | | | |
| | e toxicity ful if swallowed. | | | | | | |
| Produ Acute | <u>uct:</u> oral toxicity | : | : Acute toxicity estimate: 875.04 mg/kg Method: Calculation method | | | | |
| <u>Comr</u> | oonents: | | | | | | |
| Fidax | omicin: | | | | | | |
| Acute | oral toxicity | : | LD50 (Rat): > 1, | 000 mg/kg | | | |
| | | | LD50 (Dog): > 12 | 20 mg/kg | | | |
| | toxicity (other routes of istration) | : | LD50 (Rat): 200 Application Rout | | | | |
| Cellul | lose: | | | | | | |
| 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 | | | | |
| | | | • | | | | |



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| Sodiu | m benzoate: | | | | |
| Acute | oral toxicity | : | LD50 (Rat): > 2 Assessment: T icity | 2,000 mg/kg The substance or mixture has no acute oral to | |
| 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 derr toxicity | | |
| | corrosion/irritation assified based on av | ailable | information. | | |
| <u>Comp</u> | onents: | | | | |
| Sodiu | m benzoate: | | | | |
| Specie | | : | Rabbit | | |
| Metho Result | | : | OECD Test Gu No skin irritatio | | |
| Citric | acid: | | | | |
| Specie | es | : | Rabbit | | |
| Metho Result | | : | : OECD Test Guideline 404 : No skin irritation | | |
| Seriou | u s eye damage/eye assified based on av | | on | | |
| | onents: | anabio | | | |
| Sodiu | m benzoate: | | | | |
| Specie | es | : | Rabbit | | |
| Result | t | : | | es, reversing within 21 days | |
| Metho | d | : | OECD Test Gu | Jideline 405 | |
| Citric | acid: | | | | |
| Specie | | : | Rabbit | | |
| Result Metho | | : | Irritation to eye OECD Test Gu | es, reversing within 21 days | |
| weino | u . | • | UEUD Test Gl | | |
| Respi | ratory or skin sens | itizatio | n | | |
| Skin s | sensitization | | | | |
| | assified based on av | | | | |

Not classified based on available information.



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| Resp | iratory sensitizatio | n | | |
| Not c | lassified based on a | vailable inform | ation. | |
| Com | oonents: | | | |
| Sodiu | um benzoate: | | | |
| Test | | | | e assay (LLNA) |
| Route Speci | es of exposure | : Skin o : Mous | contact | |
| Resu | | : negat | - | |
| Rema | arks | | | om similar materials |
| | cell mutagenicity | | | |
| | lassified based on a ponents: | vailable inform | ation. | |
| | somicin: | | | |
| | toxicity in vitro | : Test | Type: Bacto | erial reverse mutation assay (AMES) |
| Cono | | | It: negative | |
| | | | | mosome aberration test in vitro |
| | | | system: Ch lt: positive | inese hamster ovary cells |
| Geno | toxicity in vivo | | Type: Mam enetic assa | malian erythrocyte micronucleus test (in vivo |
| | | | ies: Rat | y) |
| | | Applic | cation Rout | e: Intravenous |
| | | Resu | It: negative | |
| | | | Type: come | et assay |
| | | | ies: Rat | |
| | | Resu | lt: negative | |
| Cellu | lose: | | | |
| Geno | toxicity in vitro | | | erial reverse mutation assay (AMES) |
| | | Resu | It: negative | |
| | | | Type: In vit lt: negative | ro mammalian cell gene mutation test |
| Geno | toxicity in vivo | | | malian erythrocyte micronucleus test (in vivo |
| | | | enetic assa ies: Mouse | ay) |
| | | | | e: Ingestion |
| | | | lt: negative | 2 |
| Sodiı | um benzoate: | | | |
| | toxicity in vitro | : Test | Type: Bact | erial reverse mutation assay (AMES) |
| | - | | It: negative | |
| | | Tact - | Type: Chro | mosome aberration test in vitro |
| | | 1001 | · ,po. 0110 | |
| | | | | |



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| | | | 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: | | | | |
| Genot | toxicity in vitro | : | Test Type: Bacte Result: negative | rial reverse mutation assay (AMES) | |
| | | | Test Type: in vitre Result: positive | o micronucleus test | |
| | | | Test Type: Bacte Result: negative | rial reverse mutation assay (AMES) | |
| Genotoxicity in vivo | | : | Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Rat Application Route: Ingestion Result: negative | | |
| | | | | | |
| | nogenicity assified based on availa | able | information. | | |
| Not cl | nogenicity assified based on availa ponents: | able | information. | | |
| Not cl | assified based on availa | able | information. | | |
| Not cla <u>Comp</u> | assified based on availa ponents: lose: | able : | information. Rat | | |
| Not cla Comp Cellul Specia Applic | assified based on availa ponents: lose: es cation Route | able : | Rat Ingestion | | |
| Not cla Comp Cellul Specia Applic | assified based on availa <u>conents:</u> lose: es cation Route sure time | able : : : | Rat | | |
| Not cli Comp Cellul Specie Applic Expos Resul | assified based on availa <u>conents:</u> lose: es cation Route sure time | able : : : | Rat Ingestion 72 weeks | | |
| Not cla Comp Cellul Specie Applic Expos Result Sodiu Specie | assified based on availa <u>conents:</u> lose: es cation Route sure time t im benzoate: es | able : : : | Rat Ingestion 72 weeks negative Rat | | |
| Not cla Comp Cellul Specia Applic Expos Result Sodiu Specia Applic | assified based on availa conents: lose: es cation Route sure time t im benzoate: es cation Route | able : : : | Rat Ingestion 72 weeks negative Rat Ingestion | | |
| Not cla Comp Cellul Specia Applic Expos Result Sodiu Specia Applic | assified based on availa conents: lose: es cation Route sure time t im benzoate: es cation Route sure time | able : : : : : | Rat Ingestion 72 weeks negative Rat | | |
| Not cla Comp Cellul Specie Applic Expos Result Specie Applic Expos Result | assified based on availa conents: lose: es cation Route sure time t im benzoate: es cation Route sure time | able : : : : | Rat Ingestion 72 weeks negative Rat Ingestion 24 month(s) | | |
| Not cla Comp Cellul Specie Applic Expos Result Specie Applic Expos Result Repro | assified based on availa <u>conents:</u> lose: es cation Route sure time t im benzoate: es cation Route sure time t t | | Rat Ingestion 72 weeks negative Rat Ingestion 24 month(s) negative | | |
| Not cla Comp Cellul Specia Applic Expos Result Specia Applic Expos Result Repro | assified based on availa conents: lose: es cation Route sure time t im benzoate: es cation Route sure time t benzoate: es cation Route sure time t | | Rat Ingestion 72 weeks negative Rat Ingestion 24 month(s) negative | | |
| Not cla <u>Comp</u> Cellul Specie Applic Expose Result Sodiu Specie Applic Expose Result Repro Not cla <u>Comp</u> | assified based on availa conents: lose: es cation Route sure time t im benzoate: es cation Route sure time t buttive toxicity assified based on availa | | Rat Ingestion 72 weeks negative Rat Ingestion 24 month(s) negative | | |
| Not cla Comp Cellul Specie Applic Expose Result Sodiu Specie Applic Expose Result Repro Not cla Comp Fidax | assified based on availa <u>conents:</u> lose: es cation Route sure time t im benzoate: es cation Route sure time t buttive toxicity assified based on availa <u>conents:</u> | | Rat Ingestion 72 weeks negative Rat Ingestion 24 month(s) negative information. Test Type: Fertili Species: Rat Application Route | ty/early embryonic development e: Intravenous injection 6.3 mg/kg body weight | |



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| | | | Developmental T | e: Intravenous injection Foxicity: NOAEL: 12.6 mg/kg body weight Inificant adverse effects were reported |
| | | | Species: Rabbit Application Rout Developmental T | ryo-fetal development e: Intravenous injection Foxicity: NOAEL: 7 mg/kg body weight nificant adverse effects were reported |
| Cellu | lose: | | | |
| Effect | s on fertility | : | Test Type: One- Species: Rat Application Rout Result: negative | generation reproduction toxicity study e: Ingestion |
| Effect | s on fetal development | : | Test Type: Fertili Species: Rat Application Rout Result: negative | ity/early embryonic development e: Ingestion |
| Sodiu | ım benzoate: | | | |
| Effect | s on fertility | : | Species: Rat Application Rout Result: negative | generation reproduction toxicity study e: Ingestion I on data from similar materials |
| Effect | s on fetal development | : | Test Type: Embr Species: Rat Application Rout Result: negative | yo-fetal development e: Ingestion |
| Citric | acid: | | | |
| | s on fetal development | : | Test Type: One- Species: Rat Application Rout Result: negative | generation reproduction toxicity study e: Ingestion |
| | -single exposure | | | |
| | assified based on availa | able | information. | |
| | <u>oonents:</u> | | | |
| | acid: | | | ratory irritation. |



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| Repe | ated dose toxicity | | | |
| <u>Com</u> | oonents: | | | |
| Fidax | omicin: | | | |
| Speci | es | : Rat | | |
| NOAE | | | ng/kg | |
| | cation Route | : Oral | | |
| Expos Rema | sure time | : 28 E | | duaraa offacto wara rapartad |
| Rema | IIKS | . 110 8 | significant ac | dverse effects were reported |
| Speci | | : Rat | | |
| NOAE | | | 5 mg/kg | |
| | cation Route sure time | : Intra : 14 D | avenous | |
| Expos | | . 14 L | , | |
| Speci | | : Dog | | |
| NOAE | | : 9,60 : Oral |)0 mg/kg | |
| | cation Route sure time | : 3 M | | |
| Symp | | | niting | |
| Rema | | | | dverse effects were reported |
| Speci | es | : Mon | ıkev | |
| NOAE | | | ng/kg | |
| Applic | cation Route | : Oral | | |
| | sure time | : 28 C | | |
| Rema | arks | : No s | significant ac | dverse effects were reported |
| Speci | | | enile rat | |
| NOAE | | | mg/kg | |
| | cation Route | : Oral : 28 D | | |
| Rema | sure time | - | | dverse effects were reported |
| Reme | | . 110 0 | significant ac | |
| Cellu | lose: | | | |
| Speci | | : Rat | | |
| NOAE | | | 9,000 mg/kg | |
| | cation Route sure time | : Inge : 90 E | estion Davs | |
| Expos | | . 90 L | /ays | |
| Sodiu | ım benzoate: | | | |
| Speci | es | : Rat | | |
| NOAE | EL | |)0 mg/kg | |
| | cation Route | | estion | |
| Expos | sure time | : 24 N | Nonths | |
| Citric | acid: | | | |
| Speci | | : Rat | | |
| NOAE | | |)0 mg/kg | |
| LOAE | E | : 8,00 |)0 mg/kg | |
| | cation Route | | estion | |
| Expos | sure time | : 10 E | Days | |



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| - | ation toxicity assified based on availa | ble | information. | |
| Exper | ience with human exp | osı | ire | |
| Comp | onents: | | | |
| Fidax | omicin: | | | |
| Ingest | ion | : | Symptoms: Abo | dominal pain, Nausea, Vomiting, constipation |
| SECTION | 12. ECOLOGICAL INFO | ORI | ATION | |
| Ecoto | oxicity | | | |
| Comp | onents: | | | |
| Fidax | omicin: | | | |
| Toxici [;] plants | ty 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. |
| Toxici icity) | icity) Exposure time: Method: OECD | | | ales promelas (fathead minnow)): 8.91 mg/l 32 d Test Guideline 210 oxicity at the limit of solubility. |
| | ty to daphnia and other ic invertebrates (Chron- city) | | Exposure time: | a magna (Water flea)): 19.6 mg/l 21 d Test Guideline 211 |
| Toxici | ty to microorganisms | : | | |
| | | | | |
| Cellul | ose: | | | |
| | ty to fish | : | Exposure time: | latipes (Japanese medaka)): > 100 mg/l 48 h d on data from similar materials |
| Sodiu | m benzoate: | | | |



| : 484 mg/l |
|----------------|
| |
| (1 |
| algae)): > 100 |
| algae)): 32 |
| |
| : > 100 mg/l |
| 1 |
| |
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| Citric | c acid: | | | |
| | tion coefficient: n- nol/water | : log Pow: -1.72 | | |
| Mobi | ility in soil | | | |
| <u>Com</u> | ponents: | | | |
| Fida | xomicin: | | | |
| | bution among environ- al compartments | : log Koc: 0.80 | | |
| Othe | r adverse effects | | | |
| No da | ata available | | | |

SECTION 13. DISPOSAL CONSIDERATIONS

| Disposal methods | | |
|------------------------|---|--|
| Waste from residues | : | Do not dispose of waste into sewer. Dispose of in accordance with local regulations. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. |

SECTION 14. TRANSPORT INFORMATION

International Regulations

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

NOM-002-SCT Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Federal Law for the control of chemical precursors, : Not applicable essential chemical products and machinery for producing capsules, tablets and pills.



Fidaxomicin Solid Formulation

| Version 2.2 | Revision Date: 30.09.2023 | | DS Number: 250798-00008 | Date of last issue: 04.04.2023 Date of first issue: 15.08.2019 | | | | |
|----------------------|------------------------------------|------|---|---|--|--|--|--|
| The i AICS | | | t are reported in th not determined | ne following inventories: | | | | |
| DSL | | : | not determined | | | | | |
| IECS | C | : | not determined | | | | | |
| | | | | | | | | |
| SECTION | 16. OTHER INFORMAT | ΓΙΟΙ | N | | | | | |
| | sion Date format | : | 30.09.2023 dd.mm.yyyy | | | | | |
| Full t | Full text of other abbreviations | | | | | | | |
| ACG NOM | IH -010-STPS-2014 | : | Mexico. Norm NC the Work Environ | eshold Limit Values (TLV) M-010-STPS-2014 on Chemicals Polluting ment - Identification, Assessment and Con- Occupational Exposure Limits | | | | |
| | IH / TWA -010-STPS-2014 / VLE- | : | 8-hour, time-weig | hted average | | | | |

PPT

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System



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|---------|---|---------------|--|
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| comp | ces of key data used to ile the Material Safety Sheet | | al data, data from raw material SDSs, OECD earch results and European Chemicals Agen- europa.eu/ |

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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