1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifiers
   - Product name: Fidaxomicin
   - Product Catalogue Number: 314225
   - Brand: MedKoo Biosciences
   - CAS-No: 873857-62-6

1.2 Relevant identified uses of the substance or mixture and uses advised against
   - Identified uses: Laboratory chemicals, Synthesis of substances.

1.3 Details of the supplier of the safety data sheet
   - Company: MedKoo Biosciences, Inc.
   - 2500 Gateway Centre Blvd. Suite 400, Morrisville, NC27560, USA
   - Telephone: 919-636-5577
   - Fax: 919-980-4831

1.4 Emergency telephone number
   - Emergency Phone #: 911 (in USA) or local emergency phone#

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture
   - GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)
     - Skin irritation (Category 2), H315
     - Serious eye damage (Category 1), H318
     - Respiratory sensitisation (Category 1), H334
     - Skin sensitisation (Category 1), H317
     - Germ cell mutagenicity (Category 2), H341
     - Reproductive toxicity (Category 2), H361
     - Specific target organ toxicity - single exposure (Category 1), H370
     - Specific target organ toxicity - single exposure (Category 3), Respiratory system, H335
     - Chronic aquatic toxicity (Category 4), H413
   - For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 GHS Label elements, including precautionary statements
   - Pictogram:
     - Signal word: Danger
     - Hazard statement(s)
       - H315: Causes skin irritation.
       - H317: May cause an allergic skin reaction
       - H318: Causes serious eye damage.
       - H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
       - H335: May cause respiratory irritation.
       - H341: Suspected of causing genetic defects.
       - H361: Suspected of damaging fertility or the unborn child.
       - H370: Causes damage to organs.
       - H413: May cause long lasting harmful effects to aquatic life.
Precautionary statement(s)

P201: Obtain special instructions before use.
P202: Do not handle until all safety precautions have been read and understood.
P260: Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.
P264: Wash skin thoroughly after handling.
P270: Do not eat, drink or smoke when using this product.
P271: Use only outdoors or in a well-ventilated area.
P272: Contaminated work clothing should not be allowed out of the workplace.
P273: Avoid release to the environment.
P280: Wear protective gloves/ eye protection/ face protection.
P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
P304 + P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310: Immediately call a POISON CENTER/doctor.
P321: Specific treatment (see supplemental first aid instructions on this label).
P333 + P313: If skin irritation or rash occurs: Get medical advice/ attention.
P362: Take off contaminated clothing and wash before reuse.
P403 + P233: Store in a well-ventilated place. Keep container tightly closed.
P405: Store locked up.
P501: Dispose of contents/ container to an approved waste disposal plant.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Synonyms: OPT80; OPT-80; OPT 80; PAR101; PAR 101; PAR-101; Dificid; Dificil; Clostomicin B1; Difimi
cin; Lippiarmycin; Tiacumicin B

Formula: Cs2H74Cl2O18

Molecular weight: 1058.04

CAS-No: 873857-62-6

Hazardous components

<table>
<thead>
<tr>
<th>Component</th>
<th>Classification</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fidaxomicin</td>
<td>Skin Irrit. 2; Eye Dam. 1; Resp. Sens. 1; Skin Sens. 1; Muta. 2; Repr. 2; STOT SE 3; Aquatic Chronic 4; H315, H317, H318, H334, H335, H341, H361, H413</td>
<td>&lt;= 100 %</td>
</tr>
</tbody>
</table>

For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact
Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

In case of eye contact
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed
The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11
4.3 Indication of any immediate medical attention and special treatment needed
No data available

5. FIREFIGHTING MEASURES

5.1 Extinguishing media
Suitable extinguishing media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture
No data available

5.3 Advice for firefighters
Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information
No data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
For personal protection see section 8.

6.2 Environmental precautions
Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections
For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling
Avoid contact with skin and eyes. Avoid formation of dust and aerosols.
Provide appropriate exhaust ventilation at places where dust is formed.
For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities
Keep container tightly closed in a dry and well-ventilated place.
Recommended storage temperature: 2 - 8 °C for short term (weeks to 3 months) or -20°C for long term (3 months to years).
Keep in a dry place.

7.3 Specific end use(s)
Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

8. EXPOSURE CONTROLS/PERSONAL PROTECTION
8.1 Control parameters
Components with workplace control parameters
Component | CAS-No. | Value | Control parameters | Basis |
--- | --- | --- | --- | --- |
Fidaxomicin | 873857-62-6 | N/A | N/A | N/A |

8.2 Exposure controls

Appropriate engineering controls
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection
Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove’s outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Full contact
Material: Nitrile rubber
Minimum layer thickness: 0.11 mm
Break through time: 480 min
Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact
Material: Nitrile rubber
Minimum layer thickness: 0.11 mm
Break through time: 480 min
Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Data source
KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374. If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection
Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection
Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure
Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties
- a) Appearance Form: Color: White to off-white
  Form: solid powder
- b) Odour: No data available
- c) Odour Threshold: No data available
9.2 Other safety information
No data available

10. STABILITY AND REACTIVITY

10.1 Reactivity: No data available

10.2 Chemical stability: Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions: No data available

10.4 Conditions to avoid: No data available

10.5 Incompatible materials: No data available

10.6 Hazardous decomposition products
Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides (NOx)
Other decomposition products - No data available
In the event of fire: see section 5

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: No data available
Inhalation: No data available
Inhalation: Irritating to respiratory system.
Dermal: No data available

Skin corrosion/irritation: No data available
Serious eye damage/eye irritation: No data available

Respiratory or skin sensitisation
Germ cell mutagenicity: No data available
Hamster: No data available
Carcinogenicity
IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity
Reproductive toxicity - Rat - No data available
Maternal Effects: No data available
Reproductive toxicity - Rat - No data available
Effects on Newborn: No data available
Developmental Toxicity - Rat - No data available
Specific Developmental Abnormalities: No data available

Specific target organ toxicity - single exposure
Inhalation - May cause respiratory irritation.

Specific target organ toxicity - repeated exposure: No data available

Aspiration hazard: No data available

Additional Information
RTECS: DA8340700
Alopecia., Liver injury may occur., Kidney injury may occur., Nausea, Headache, Vomiting, bone marrow depression
Stomach - Irregularities - No data available
Central nervous system - No data available
Kidney - Irregularities - No data available
Heart - Irregularities - No data available
Stomach - Irregularities - No data available
Stomach - Irregularities - No data available
Kidney - Irregularities - No data available
Stomach - Irregularities - No data available

12. ECOLOGICAL INFORMATION

12.1 Toxicity: No data available

12.2 Persistence and degradability: No data available

12.3 Bioaccumulative potential: No data available

12.4 Mobility in soil: No data available

12.5 Results of PBT and vPvB assessment
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects: No data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods
**Product**
Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

**Contaminated packaging**
Dispose of as unused product.

14. **TRANSPORT INFORMATION**

**DOT (US):** Not dangerous goods  
**IMDG:** Not dangerous goods  
**IATA:** Not dangerous goods

15. **REGULATORY INFORMATION**

**SARA 302 Components**
No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

**SARA 313 Components**
No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 313.

**SARA 311/312 Hazards**
Acute Health Hazard, Chronic Health Hazard

**Massachusetts Right To Know Components**

<table>
<thead>
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**Pennsylvania Right To Know Components**

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**New Jersey Right To Know Components**

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**California Prop. 65 Components**

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16. **OTHER INFORMATION**

**Full text of H-Statements referred to under sections 2 and 3.**

- **Acute Tox.** Acute toxicity  
- **Aquatic Chronic** Chronic aquatic toxicity  
- **Eye Dam.** Serious eye damage  
- **Eye Irrit.** Eye irritation  
- **Flam. Liq.** Flammable liquids  
- **H225** Highly flammable liquid and vapour.  
- **H301 + H311 + H331** Toxic if swallowed, in contact with skin or if inhaled  
- **H315** Causes skin irritation.  
- **H317** May cause an allergic skin reaction.  
- **H318** Causes serious eye damage.
H319 Causes serious eye irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.
H341 Suspected of causing genetic defects.
H361 Suspected of damaging fertility or the unborn child.
H370 Causes damage to organs.
H413 May cause long lasting harmful effects to aquatic life.
Muta. Germ cell mutagenicity
Repr. Reproductive toxicity
Resp. Sens. Respiratory sensitisation
Skin Irrit. Skin irritation
Skin Sens. Skin sensitisation
STOT SE Specific target organ toxicity - single exposure

HMIS Rating
Health hazard: 2
Chronic Health Hazard: *
Flammability: 0
Physical Hazard 0

NFPA Rating
Health hazard: 2
Fire Hazard: 0
Reactivity Hazard: 0

Further information
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Preparation Information
MedKoo Biosciences, Inc.
Product Safety – multiple Region
Tel: 919-636-5577

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