


 Safety Data Sheet: Fidaxomicin from Fermentek
1. Identification of the substance/mixture and of the Company
1.1. Product identifiers

Product name	<i>Fidaxomicin</i>	Formula	<i>C₅₂H₇₄Cl₂O₁₈</i>
Product Code	<i>FI</i>	RTECS	<i>N.A.</i>
CAS #	<i>873857-62-6</i>	Molecular weight	<i>1058.00</i>
EC Number #	<i>692-555-6</i>	Substance? Mixture?	<i>Substance</i>
Synonyms	<i>Clostomicin B1</i>	<i>Tiacumicin B</i>	<i>Lipiarmycin A3</i>
Source	<i>Dactylosporangium aurantiacum</i>	Date of version	<i>28 December, 2020</i>

1.2. Intended uses of the substance or mixture and uses advised against

1.2.1. Intended use:	1.2.2. Uses advised against:
<ul style="list-style-type: none"> • Research and development. • Laboratory reagent. • To be used by professionals only 	<ul style="list-style-type: none"> • Not for drug, • Not to be used in humans or animals. • Not food additive

1.3. Details of the supplier of the SDS

FERMENTEK Ltd
 4 Yatziv street, POB 47120
 Jerusalem 97800,
 Israel

Tel: +972 2 5853953
 Fax: +972 2 5853943
 eMail: fermentek@fermentek.com
 Website: www.fermentek.com

1.4. Emergency Telephone number

For chemical emergency spill, leak, fire, exposure, or accident calls CHEMTREC day or night:
 Within USA and Canada: 1-800-424-9300. Outside USA and Canada: +1 703-527-3887

This company is the manufacturer of the product, and the supplier of the safety data sheet

1.5. Reach:

See section 15

2. Hazards identification
2.1. Classification of the substance
2.1.1. GHS Classification According to EU Reg. 1272/2008 and US OSHA 1910.1200)

Acute toxicity, Oral	(Category 4)	H302 Harmful if swallowed
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2.2. GHS Label elements, including precautionary statements

2.2.1. Pictogram: {  }

2.2.2. Signal word { **Warning** }

2.2.3. GHS Hazard Statements

H302	Harmful if swallowed
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2.2.4. GHS Precautionary Statements

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 {hands} thoroughly after handling.
P270	Do not eat, drink or smoke when using this product
P284	Wear respiratory protection

2.2.5.GHS Response Phrases

P301+P312	If swallowed: Call a poison center/doctor
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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.
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3. Composition/information on ingredients

Substance	
Substance name:	<i>Fidaxomicin</i>
Concentration	100%
CAS Registry#:	873857-62-6
EC#:	692-555-6
Molecular Formula:	C52H74Cl2O18
Molecular Weight:	1058.00
Classification	Acute toxicity, Oral (Category 4),
Mixture?	Substance.

4. First Aid Measures

4.1.Description of First Aid Measures

General advice:	If medical attention is required, show this safety data sheet to the doctor
Inhalation:	If inhaled, move person into fresh air. If not breathing, give artificial respiration.
Ingestion:	Never give anything by mouth to an unconscious person. Rinse mouth with water. Do NOT induce vomiting unless advised to do so by a physician or Poison Control Center. Seek medical attention.
Skin Contact:	Wash affected area with soap and water. Consult a physician if any exposure symptoms are observed
Eye contact:	Rinse eyes with plenty of water as a precaution.

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

	No information available
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4.3.Indication of any immediate medical attention and special treatment needed

	No information available
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5. Fire-fighting measures

5.1.Extinguishing media

Suitable extinguishing media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Unsuitable extinguishing media	None known

5.2.Other information

Hazardous combustion products	Carbon oxides; Nitrogen oxides
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Advice for firefighters	Wear self-contained breathing apparatus for fire fighting if necessary. Wear protective suit.
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6. Accidental release measures

6.1. Personal precautions, protective equipment, and emergency procedures

Personal precautions	Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. Keep people away from and upwind of spill/leak.
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6.2. Environmental precautions

Environmental precautions	Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.
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6.3. Methods and material for containment and cleaning up

Methods for containment:	Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or tarp to minimize spreading. Dike far ahead of liquid spill for later disposal.
Methods for cleaning up:	Clean-up should be dealt with only by qualified personnel familiar with the specific substance. Cover liquid spill with sand, earth or other non-combustible absorbent material (e.g. sand, earth, diatomaceous earth, and vermiculite). Cover powder spill with plastic sheet or tarp to minimize spreading. Sweep up and shovel into suitable containers for disposal.

7. Handling and storage

7.1. Precautions for safe handling

Advice on safe handling:	Avoid contact with skin, eyes, or clothing. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink, or smoke when using this product.
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7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions:	Keep container tightly closed in a dry and well-ventilated place. Store at -20 °C. Some other manufacturers may advice storing temperature 2-8°C.
Suitable packaging	
Incompatible materials:	None known based on information available.

8. Exposure Controls/Personal Protection

8.1. Control parameters

Control parameters	Components with workplace control parameters
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8.2. Exposure controls

Appropriate engineering controls	Showers, Eyewash stations, Ventilation systems Avoid contact with skin, eyes, and clothing. Wash hands before breaks and immediately after handling the product. Use fumehood for routine work.
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8.3. Personal protective equipment

[PPE=Personal Protection Equipment]

PPE: Respiratory protection	Where risk assessment shows air-purifying respirators are appropriate use a fullface 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).
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PPE: Hand Protection:	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal techniques to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices, and wash and dry hands
PPE: Eye Protection:	Use a 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)
PPE: Skin and Body 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. The selected protective gloves must satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

9. Physical and chemical properties

9.1. Physical / chemical properties

Physical State at room temperature	Solid / powder
Color	White to off-white
No further safety relevant data are available	

10. Stability and reactivity

Reactivity:	No information available.
Chemical stability:	Stable under normal conditions.
Conditions to avoid	Heat, flames, and sparks. Sunlight.
Incompatible materials	Strong reducers and oxidizers
Possibility of Hazardous Reactions	None under normal processing
Hazardous decomposition products	Carbon oxides.

11. Toxicological information

11.1. Information on toxicological effects

The toxicological effects of this product have not been thoroughly studied.

11.1.1. Acute Toxicity	
Oral	LD50 Oral - Rat - >1000 mg/kg
Skin corrosion/irritation:	No data available
Skin corrosion/irritation:	No data available
Serious eye damage/eye irritation:	No data available
Respiratory or skin sensitization/corrosion:	No data available
11.1.2. CMR hazards	
In vitro data	Causes mutations in bacteria in vitro
Germ cell mutagenicity:	No data available
Carcinogenicity:	No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity / Teratogenicity:	No data available
STOT-SE – single exposure (GHS):	No data available
STOT-SE – repeated exposure (GHS):	No data available
Aspiration hazard:	No data available



11.1.3. *Potential Health Effects and Routes of Exposure*

If Inhaled	No data available
If swallowed	No data available
If on skin	No data available
If in Eyes	No data available

11.2. *Additional information*

RTECS number	No data available
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12. *Ecological Information*

Eco-Toxicity	No further relevant information available
Other adverse effects	No further relevant information available.

13. *Disposal Considerations*

13.1. *Waste treatment methods*

Waste from residues / unused products	Dispose of in accordance with local regulations
Contaminated packaging	Dispose of as unused product

14. *Transport information*

14.1. *UN number, Proper Shipping Name, Transport Hazard Class, packing group*

	US DOT	IATA	IMDG	ADR/RID
UN Number UN proper shipping name	Not hazardous goods Not regulated (Fidaxomicin)	Not hazardous goods Not regulated (Fidaxomicin)	Not hazardous goods Not regulated (Fidaxomicin)	Not hazardous goods Not regulated (Fidaxomicin)
Transport Hazard Class & Packing Group	Not applicable	Not applicable	Not applicable	Not applicable
			Not marine pollutant	

14.2. *Additional information*

Excepted quantities (EQ)	Not applicable
De Minimis exemption	Not applicable

15. *Regulatory information*

15.1. *Product-specific safety, health, and environmental regulations/legislation*

USA EPA / TSCA	This product is not listed on the USA EPA TSCA (it is for research)
California proposit. 65	This product is not listed on California proposit. 65 as on Jan 3, 2020
EU ECHA Status	This product is registered with the EU ECHA, Number 692-555-6 REACH: Not registered ANNEX III: Not Listed
Canada	This product is not listed on the Canadian DSL/NDSL

16. *Other information*

16.1. *Date of revision:*

<ul style="list-style-type: none"> Monday, 28 December, 2020 11:12



16.2. Department issuing this SDS

- Quality systems and regulatory affairs

16.3. General Disclaimer

- 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 given here is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification.
- The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

16.4. The users'/employers' responsibility

- A risk assessment should be performed by the employer/user prior to use of this product.
- All recommendations included in this document, are advisory in nature.
- The type of protective equipment must be selected based on the amount and concentration of all dangerous materials being used in the workplace.

16.5. End of SDS