



Fidaxomicin

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1. Identification of the Substance and the Manufacturer

1.1. Product identifiers

Product name	Fidaxomicin	Formula	$C_{52}H_{74}Cl_2O_{18}$
Product Code	FID-001	Molecular weight	1058.0 g/mol
CAS	873857-62-6	Mixture?	Substance
ECHA	692-555-6	PUBCHEM	10034073
Drug bank	drugs/DB08874	RTECS	Not Listed 8-2024
Comptox EPA	DTXSID901016415	CHEBI	CHEBI:68590

Synonyms and other names	Dificid	Clostomicin B1	lipiarmicin	lipiarmycin A3	tiacumicin B
	[[2R,3S,4S,5S,6R)-6-[[[(3E,5E,8S,9E,11S,12R,13E,15E,18S)-12-[(2R,3S,4R,5S)-3,4-dihydroxy-6,6-dimethyl-5-(2-methylpropanoyloxy)oxan-2-yl]oxy-11-ethyl-8-hydroxy-18-[(1R)-1-hydroxyethyl]-9,13,15-trimethyl-2-oxo-1-oxacyclooctadeca-3,5,9,13,15-pentaen-3-yl]methoxy]-4-hydroxy-5-methoxy-2-methyloxan-3-yl] 3,5-dichloro-2-ethyl-4,6-dihydroxybenzoate				

Source	From: <i>Dactylosporangium aurantiacum</i> (an Actinobacterium)	Version Date	26 September, 2024
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1.2. Intended uses of the Substance and uses advised against

1.2.1. Intended use:	1.2.2. Uses advised against:
Research and development. Laboratory reagent. Reference material.	Manufacturing of substances. To be used by professionals only
	Not a drug, Not a food additive Not to be used in humans or animals.

1.3. Contacts

1.3.1. Details of the supplier of the SDS
<p>FERMENTEK ltd 4 Yatziv street, POB 47120 Jerusalem 97800, Israel</p> <p>Tel: +972 2 5853953 Fax: +972 2 5853943 eMail: Fermentek@Fermentek.com Safety@Fermentek.com Website: Fermentek.com</p>

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

1.3.2. 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





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2. Hazards' identification.

2.1. Classification of the Substance .

To our judgement, hazards of this substance have not been thoroughly investigated
Other authors have classified this substance as H300, H310, H330 (Fatal if swallowed, inhaled or in contact with skin, and H350 may cause cancer. To our opinion, these claims are neither proven experimentally, nor based on available literature

2.1.1. GHS Classification: According to EU Reg. 1272/2008 and US OSHA 1910.1200)

Accute toxicity: Oral	Category 4	H302	Harmful if swallowed (based on estimate)
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2.2. GHS Label elements, including precautionary statements

2.2.1. Pictogram:  Signal word: {Warning}

2.2.2. Hazard Statements

H302	Harmful if swallowed
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2.2.3. GHS Precautionary Statements

P203	Obtain, read and follow all safety instructions before use.
P261	Avoid breathing dust or mist.
P264	Wash {hands} thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection

2.2.4. GHS Response Phrases:

P330; P301+P312	IF SWALLOWED, Rinse mouth. Call a POISON CENTER/doctor if you feel unwell.
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3. Composition/information on ingredients

Substance	
Substance Name:	Fidaxomicin
Concentration	<=100%
CAS Registry#:	873857-62-6
EC#:	692-555-6
Molecular Formula:	C ₅₂ H ₇₄ Cl ₂ O ₁₈
Molecular Weight:	1058.0 g/mol
Classification	Acc O:4 (H302)





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Mixture?	Substance
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4. First Aid Measures.

4.1. Description of First Aid Measures.

General advice:	First-aiders need to protect themselves. If medical attention is required, show this safety data sheet to the doctor in attendance.
Ingestion:	If swallowed: give water to drink (two glasses at most). Seek medical advice immediately.

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

General symptoms	See section 11
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	No data 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, C ₅₂ H ₇₄ Cl ₂ O ₁₈
Advice for firefighters	Wear self-contained breathing apparatus for fire fighting if necessary. Wear protective suit.

6. Accidental release measures

6.1. Personal precautions, protective equipment, and emergency procedures

Personal precautions	Use personal protective equipment as required. 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 the powder spill with a 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 the powder spill with a 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. Keep out of the reach of children. Store at -20 °C.
Suitable packaging	Must only be kept in original packaging.
Incompatible materials:	None known based on information available.

8. Exposure Controls/Personal Protection

Attention:

Usually, the product of concern would be present at the intended workplace in miniscule amounts, while surrounded by considerable amounts of other flammable, toxic or otherwise hazardous substances. Therefore, the employer/user should perform a risk assessment prior to the use of this product.

The type of protective equipment must be selected based on the amount and concentration of all dangerous materials being used in the workplace.

All recommendations included in this document are advisory in nature

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 fume-hood 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 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).
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 have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

9. Physical and chemical properties

The information given here does not purport specification of warranty of any kind. It 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.

9.1. Physical/chemical properties

Physical State at room temperature	Solid
Appearance	White to Off-White powder
No further safety relevant data are available	





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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 combustion products	See section 5

11. Toxicological information

11.1. Information on toxicological effects

To the best of our knowledge, the toxicological effects of this product have not been thoroughly studied yet.

11.1.1. Acute Toxicity

Acute toxicity:	<p>▶▶Estimate ◀◀ Oral, Mouse, LD50>1500mg/kg Intravenous , Rat, LD50=200 mg/kg Oral , Rat, LD50>1000 mg/kg No other acute toxicity available.</p>
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. Chronic toxicity

Chronic toxicity	No data available
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11.1.3. CRM (Carcinogene, Mutagene, Reproductive hazards)

Germ cell mutagenicity:	No data available
Carcinogenicity:	Not classified by IARC
Reproductive toxicity / Teratogenicity:	No data available

11.2. Additional information

RTECS number	Not Listed 8-2024
General symptoms	No data available

12. Ecological Information

Eco-Toxicity	No data available
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Other adverse effects No data available

13. Disposal Considerations

13.1. Waste treatment methods

Waste Disposal 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

	IATA	IMDG	ADR/RID	US/DOT
UN Number, Proper shipment name	Not classified Not regulated (Fidaxomicin)	Not classified Not regulated (Fidaxomicin)	Not classified Not regulated (Fidaxomicin)	Not classified Not regulated (Fidaxomicin)
Transport hazard Class, Packing group	Not hazardous for transport	Not hazardous for transport	Not hazardous for transport	Not hazardous for transport
Comments		Not marine pollutant		

15. Regulatory information

15.1. Safety, health, and environmental regulations/legislation

USA EPA / TSCA This product is not listed on the USA EPA TSCA (it is for research)

EU ECHA Status This product is registered with the EU ECHA, Number 692-555-6
REACH: Neither Registered nor PreRegistered.
ANNEX III (criteria for 1 - 10 tonne registered substances): Not Listed

16. Other information

16.1. Version information

Version date:8-2024 Toxicity revised. Not hazardous for transport. No reprotox.

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.**





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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 explicitly specified in the text.

16.4. The users'/employers' responsibility:

Usually, the product of concern would be present at the intended workplace in miniscule amounts, while surrounded by considerable amounts of other flammable, toxic or otherwise hazardous substances.

Therefore, the employer/user should perform a risk assessment by prior to the use of this product. The type of protective equipment must be selected based on the amount and concentration of all dangerous materials being used in the workplace.

All recommendations included in this document are advisory in nature.

16.5. No ©copyright



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16.6. End of SDS






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16.7. Appendix A : Abbreviations and acronyms:

	This symbol means, the text looking like a hyperlink, is a clickable link indeed. Of course, these are only active on glass screens, not on paper.
From /Synthetic /Semisynthetic	“From” means the compound was extracted from biomass, whether algal, fungal, microbial or plant material “Synthetic” means this compound has been manufactured by chemical conversion of another compound. Often, certain product is made by the method of microbial fermentation, purified, and then chemically converted into another compound. It may be called “semisynthetic”.
Mixture/Substance/Complex	Substance means a single compound. , Mixture means there are two or more pure substances mixed purposely. Complex is a mixture of two or more substances which naturally occur together and are sold unseparated
Acute Tox.:	Acute toxicity
CAS:	Chemical Abstracts Service
ChEBI	Chemical Entities of Biological Interest
Comptox	CompTox Chemicals Dashboard Resource Hub (EPA)
DOT:	US Department of Transportation
ECHA	European Chemicals Agency
EINECS:	European Inventory of Existing Commercial Chemical Substances
EPA	United States Environmental Protection Agency
Eye Dam.:	Serious eye damage/eye irritation
HSDB	Hazardous Substances Data Bank
HMIS:	Hazardous Materials Identification System (USA)
IATA:	International Air Transport Association
IMDG:	International Maritime Code for Dangerous Goods
LC50:	Lethal concentration, Median
LD50:	Lethal dose, Median
LDL0	Letal dose, leatst published
NDG	Not dangerous goods (for transport)
NFPA:	National Fire Protection Association USA
NIOSH:	National Institute for Occupational Safety
NOAEL	No-Observed-Adverse-Effects-Level. Highest dose which yelded no results at toxicity test
OSHA:	Occupational Safety & Health
PBT:	Persistent, Bioaccumulative, and Toxic
PEL:	Permissible Exposure Limit
PubChem	An open chemistry database at the National Institutes of Health (NIH). “
REL:	Recommended Exposure Limit
Repr.:	Reproductive toxicity, incl. hazards to reproductive systems, and pregnancy and the offspring.
RTECS:	Registry of Toxic Effects of Chemical Substances. Not free.
Skin Irrit:	Skin corrosion/irritation
STOT/SE	Specific target organ toxicity/Single exposure
STOT/RE	Specific target organ toxicity/Repeated exposure
T3DB	Toxin and Toxin Target Database
TDL0	Toxic dose, least published

