

SAFETY DATA SHEET

Cat# 2832-1, 5 Fidaxomicin

SDS DATE: Apr 23, 2019

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: FIDAXOMICIN
PRODUCT CODES: Cat# 2832-1, -5
MANUFACTURER: BioVision, Inc.
ADDRESS: 155 S. Milpitas Boulevard, Milpitas, CA 95035
EMERGENCY PHONE: 858-373-8066
CHEMTREC PHONE:
OTHER CALLS: 408-493-1800
FAX PHONE: 408-493-1801

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Product Name/Chemical Name	Description	Volume	Safety Information
FIDAXOMICIN	Solid	2832-1: 1 mg 2832-5: 5 mg	See below

SECTION 3: HAZARDS IDENTIFICATION

Components	CAS Number	EC-No.	Molecular Weight	Chemical Formula
FIDAXOMICIN	873857-62-6	--	1058.04	C ₅₂ H ₇₄ Cl ₂ O ₁₈

FIDAXOMICIN:

Emergency Overview:

OSHA Hazards: Harmful by ingestion, Irritant

GHS Classification

Acute toxicity, Oral (Category 4)

Skin irritation (Category 2)

Eye irritation (Category 2A)

Specific target organ toxicity - single exposure (Category 3)

GHS Label elements, including precautionary statements

Pictogram:



Warning

Signal word:

Hazard statement(s):

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

Precautionary statement(s):

P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ 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.

P280 Wear protective gloves/ eye protection/ face protection.

P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell.

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.

HMIS Classification

Health hazard: 2

Flammability: 0

Physical hazards: 0

NFPA Rating

Health Hazard: 2

Fire: 0

Reactivity Hazard: 0

Potential Health Effects

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.

Skin: Harmful if absorbed through skin. May cause skin irritation.

Eyes: Cause eye irritation.

Ingestion: Harmful if swallowed.

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SECTION 4: FIRST AID MEASURES

If inhaled: If breathed in, move person into fresh air. If not breathing, give artificial respiration.
In case of skin contact: Wash off with soap and plenty of water.
In case of eye contact: Flush eyes with water as a precaution.
If swallowed: Never give anything by mouth to an unconscious person. Rinse mouth with water.

5: FIRE-FIGHTING MEASURES

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Special protective equipment for fire fighters: Wear self-contained breathing apparatus for firefighting if necessary.
Hazardous combustion products: Hazardous decomposition products formed under fire conditions— see section 10.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions: Avoid dust formation. Avoid breathing vapors, mist, or gas.
Environmental precautions: Do not let product enter drains.
Methods for cleaning up: Sweep up and shovel. Keep in suitable, closed containers for disposal.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling
Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.
Conditions for safe storage
Keep container tightly closed in a dry and well-ventilated place.
Recommended storage temperature: -20 °C.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection

Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand 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.

Eye protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

Skin and body protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific workplace. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Hygiene measures

General industrial hygiene practice.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Property	FIDAXOMICIN
Appearance:	White solid
pH:	No data available
Water Solubility:	No data available
Other Solubility:	DMSO
Boiling Point (°C):	No data available
Melting Point (°C):	No data available
Flash Point (°C):	No data available
Ignition Temperature (°C):	No data available
Density:	No data available

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SECTION 10: STABILITY AND REACTIVITY

Property	FIDAXOMICIN
Chemical stability	Stable under recommended storage conditions
Conditions to avoid:	No data available
Materials to avoid:	Strong oxidizing agents
Hazardous decomposition products:	Carbon oxides, hydrogen chloride gas

SECTION 11: TOXICOLOGICAL INFORMATION

FIDAXOMICIN:

Acute toxicity: No data available

Skin corrosion/irritation: no data available

Serious eye damage/eye irritation: no data available

Respiratory or skin sensitization: no data available

Germ cell mutagenicity: 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.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

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: no data available

Teratogenicity: no data available

Specific target organ toxicity – single exposure (GHS): Inhalation - May cause respiratory irritation.

Specific target organ toxicity – repeated exposure (GHS): no data available

Aspiration hazard: no data available

Potential Health Effects

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.

Skin: Harmful if absorbed through skin. May cause skin irritation.

Eyes: May cause eye irritation.

Ingestion: Harmful if swallowed.

Signs and Symptoms of Exposure: To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Synergistic effects: no data available

Additional information: RTECS: not available

SECTION 12: ECOLOGICAL INFORMATION

FIDAXOMICIN:

Persistence and degradability: no data available

Toxicity: no data available

Bioaccumulative potential: no data available

Mobility in soil: no data available

PBT and vPvB assessment: no data available

Other adverse effects: no data available

SECTION 13: DISPOSAL CONSIDERATIONS

Product: Observe all federal, state, and local environmental regulations.

Contaminated packaging: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

FIDAXOMICIN:

DOT (US): Not dangerous goods.

IMDG: Not dangerous goods.

IATA: Not dangerous goods.

SECTION 15: REGULATORY INFORMATION

FIDAXOMICIN:

OSHA Hazards: Harmful by ingestion, Irritant.

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

SARA 313 Components: SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title II, Section 313.

SARA 311/312 Hazards: Acute Health Hazard

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Massachusetts Right To Know Components: No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components: FIDAXOMICIN, CAS-No. 873857-62-6

New Jersey Right To Know Components: FIDAXOMICIN, CAS-No. 873857-62-6

California Prop. 65 Components: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

EU regulations

Component	Risk Phrases	Safety Phrases
FIDAXOMICIN	R28; R38; R41; R48; R62/63	S24/25; S26; S28; S36/37/39

SECTION 16: OTHER INFORMATION

DISCLAIMER:

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. BioVision, Inc., shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale.