

MATERIAL SAFETY DATA SHEET

Chemical Name: Dalbavancin for Injection 500 mg

MSDS No: MSDS/010-01

1. Identification:**Product identifier:** Dalbavancin for Injection 500 mg

Manufacturer Contact Details: Biological E Ltd,

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E-mail Address: info@biological.com.**2. Hazard(s) identification****Classification of the substance or mixture**

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

Label elements

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

Other hazards

This substance/mixture contains no components considered to be either persistent,

Bio accumulative and toxic, or very persistent and very bio accumulative at levels of 0.1 % or higher.

3. Composition/information on ingredients:

Chemical Name	CAS Number	Quantity /mL \$
Dalbavancin hydrochloride @	171500-79-1	33.33 mg *
MANNITOL USP	69-65-8	8.6 mg
LACTOSE MONOHYDRATE USP -NF	64044-51-5	8.6 mg
Sodium Hydroxide USP-NF	1310-73-2	Qs to pH 4.0-5.0
Hydrochloric Acid USP -NF	7647-01-0	Qs to pH 4.0-5.0

\$ Bulk solution concentration.

@ Dalbavancin hydrochloride equivalent to Dalbavancin as the free base.

* Quantity is calculated on basis of 100% assay and nil water content and nil chloride content.

4. First aid measures:**General advice** Call emergency medical service. Remove and isolate contaminated clothing and shoes.**Eye contact** In case of contact with substance, immediately flush skin or eyes with running water for at least 20 minutes.**Skin Contact** Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.



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Inhalation Move victim to fresh air. If breathing is irregular or stopped, administer artificial respiration. Administer oxygen if breathing is difficult.

Ingestion Consult a physician if necessary.

Note to physicians

Patients should be advised that allergic reactions, including serious allergic reactions, could occur, and that serious allergic reactions require immediate treatment. Patients should inform their healthcare provider about any previous hypersensitivity reactions to this product, or other glycopeptides.

5. Fire-fighting measures

Suitable extinguishing media

Dry chemical, CO₂, water spray or regular foam. Water spray, fog or regular foam. Move containers from fire area if you can do it without risk. Dike fire-control water for later disposal.

Unsuitable extinguishing media

Do not scatter spilled material with high-pressure water streams.

Specific hazards arising from the chemical

Some may burn but none ignites readily. Those substances designated with a "P" may polymerize explosively when heated or involved in a fire. Some may be transported hot.

Explosion data

Sensitivity to Mechanical Impact Not impact sensitive.

Sensitivity to Static Discharge Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. Accidental release measures

Personal precautions Do not touch or walk through spilled material. Stop leak if you can do it without risk.

Environmental precautions Prevent entry into waterways, sewers, basements or confined areas. See Section 12 for additional ecological information.

Methods for containment Prevent dust cloud.

Methods for cleaning up Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

7. Handling and storage

Advice on safe handling Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

Incompatible materials None known based on information supplied. Recommended storage Protect from sunlight.

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8. Exposure controls/personal protection

Control parameters

Exposure Guidelines: This product as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	OEL (pg/m3)
Dalbavancin 171500-79-1	NA	NA	NA	66

Considering this, the derived OEL value of 66 pg/m³ is considered as the final OEL value and it would be considered as an OEB 3 compound based on the 5 Band system as suggested by NIOSH [Ripple SD, Health Hazard Banding; Me Kernan, 2015],

Appropriate engineering controls

Engineering Controls The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/face protection No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.

Skin and body protection During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.)

Respiratory protection Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

9. Physical and chemical properties

Physical state	: Solid
Appearance	: Lyophilized: White to off-white to pale yellow solid;
Reconstituted	: Clear, colourless to yellow solution
Color	: White, light yellow
Odor	: Odorless
Odor threshold	: No information available
PH	: No information available
Melting point/freezing point	: Heated to ~300°C without apparent melting
Boiling point / boiling range	: No information available

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Flash point	:	No information available
Evaporation rate	:	No information available
Flammability (solid, gas)	:	No information available
Flammability Limit in Air	:	No information available
Other Information		
Molecular weight	:	1816.7
VOC Content (%)	:	No information available
Density'	:	No information available
Bulk density	:	No information available

10. Stability' and Reactivity'**Reactivity**

Not defined As Reactive substance

Chemical stability

Stable under normal conditions.

Possibility of Hazardous Reactions

None under normal processing.

Conditions to avoid

Aerosol formation.

Incompatible materials

None known based on information supplied.

Hazardous Decomposition Products

None known based on information supplied.

11. Toxicological information**Information on toxicological effects****Acute toxicity**

Oral: No data available

Inhalation: No data available

Dermal: 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

No data available

Reproductive toxicity

No data available

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Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

Additional Information

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

12. Ecological information

Toxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Results of PBT and vPvB assessment

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.

Endocrine disrupting properties

No data available

Other adverse effects

No data available

13. Disposal consideration

Waste treatment methods

Disposal of wastes: Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging: Do not reuse container. Dispose of contents/containers in accordance with local regulations.

14. Transport information

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. Regulatory information

This product is a drug and as such is regulated under the US Food and Drug Administration (FDA) International Inventories

TSCA Not listed.

DSL/NDSL Not Listed

EINECS/ELINCS Not Listed

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Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute health hazard No

Chronic Health Hazard No

Fire hazard No

Sudden release of pressure hazard No

Reactive Hazard No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive.

Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

16. Other Information:

Biological E. Limited provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. Biological E. Limited will not be responsible for damages resulting from use or reliance upon information.

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