



SAFETY DATA SHEET

Revision Date 02-Oct-2018

Version 12

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Dalvance 500mg

Other means of identification

Product Code FG00006

Synonyms Dalvance (US) and Xydalba (EU)

Recommended use of the chemical and restrictions on use

Recommended Use Antibiotic

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet

Manufacturer

Allergan plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525

E-mail address SDS@Allergan.com

Emergency telephone number

Emergency Telephone

Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Reproductive toxicity	Category 2
Specific target organ toxicity (repeated exposure)	Category 2

Label elements

Emergency Overview

Warning

Hazard statements

H361 - Suspected of damaging fertility or the unborn child

H373 - May cause damage to organs through prolonged or repeated exposure



Appearance Lyophilized: White to off-white to pale yellow solid;
Reconstituted: Clear, colorless to yellow solution

Physical state Solid

Odor Odorless

Chemical Name
Dalbavancin

Symptoms
The most common adverse reactions in patients treated with this medication are nausea, headache, and diarrhea. The median duration of adverse reactions was 4.0 days in both treatment groups. The following selected adverse reactions were reported in patients treated with this product at a rate of less than 2% in these clinical trials: Blood and lymphatic systems disorder: anemia, hemorrhagic anemia, leucopenia, neutropenia, thrombocytopenia, petechiae, eosinophilia, thrombocytosis; Gastrointestinal Disorders and administration site conditions: gastrointestinal hemorrhage, melena, hematochezia, abdominal pain; General Disorders and administration site conditions: infusion-related reactions; Hepatobiliary Disorders: hepatotoxicity; Immune System Disorder: anaphylactoid reaction; Infections and infestations: Clostridium difficile colitis, oral candidiasis, vulvovaginal mycotic infection; Investigations: hepatic transaminases increased, blood alkaline phosphatase increased, international normalized ratio increased; Metabolism and nutrition disorders: hypoglycemia; Nervous System Disorders: dizziness; Respiratory, thoracic and mediastinal disorders: bronchospasm; Skin and Subcutaneous Tissue Disorder: urticaria; Vascular Disorders: flushing, phlebitis, wound hemorrhage, spontaneous hematoma.

Chemical Name
Dalbavancin

Medical Conditions Aggravated by Exposure
Known hypersensitivity to this medication

Precautionary statements

- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P281 - Use personal protective equipment as required
- P308 + P313 - IF exposed or concerned: Get medical advice/attention
- P405 - Store locked up
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P260 - Do not breathe dust/fume/gas/mist/vapors/spray
- P314 - Get medical advice/attention if you feel unwell
- P501 - Dispose of contents/ container to an approved waste disposal plant

Other Information

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	EINECS	Weight-%
Dalbavancin	171500-79-1	N/A	40 - 70*
MANNITOL USP	69-65-8	200-711-8	10 - 30*
LACTOSE MONOHYDRATE NF(FAST FLOW)(SPRAY DRIED)	64044-51-5	N/A	10 - 30*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

First aid measures

General advice	Call 911 or 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.
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.

Chemical Name
Dalbavancin

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 ignite 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
Sensitivity to Static Discharge

Not impact sensitive.

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.

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	Allergan OEL (ug/m ³)
Dalbavancin 171500-79-1	N/A	N/A	N/A	67

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

Information on basic physical and chemical properties

Physical state	Solid	Appearance	Lyophilized: White to off-white to pale yellow solid; Reconstituted: Clear, colorless to yellow solution
Color	white, light yellow	Odor	Odorless
Odor threshold	No information available		

Property

pH
 Melting point/freezing point
 Boiling point / boiling range
 Flash point
 Evaporation rate
 Flammability (solid, gas)
 Flammability Limit in Air

Values

No information available
 No information available
 No information available
 No information available
 No information available
 No information available

Upper flammability limit:	No information available
Lower flammability limit:	No information available
Vapor pressure	No information available
Vapor density	No information available
Specific Gravity	No information available
Water solubility	Soluble in water
Solubility in other solvents	No information available
Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Explosive properties	No information available
Oxidizing properties	No information available

Other Information

Molecular weight	No information available
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 likely routes of exposure

Acute toxicity

Chemical Name	Inhalation	Eye contact	Skin Contact	Ingestion
Dalbavancin	See Symptoms for more information.	Mild eye irritation.	No known hazard in contact with skin.	See Symptoms for more information.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Dalbavancin	>2000 mg/kg (rat)	N/A	N/A
MANNITOL USP	= 13500 mg/kg (Rat)	N/A	N/A

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Dalbavancin	Not mutagenic in the standard battery of tests.	Long-term studies in animals to determine the carcinogenicity potential of this medication have not been conducted.	No treatment-related malformations or embryo-fetal toxicity were observed in pregnant rats or rabbits at clinically relevant exposures of dalbavancin. Treatment of pregnant rats with dalbavancin at 3.5 times the human dose on an	It is not known whether this drug is excreted in human milk. Because most drugs are excreted in human milk, if use of this drug is deemed essential, the patient should stop nursing.

			exposure basis during early embryonic development and from implantation to the end of lactation resulted in delayed fetal maturation and increased fetal loss, respectively.	
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Chronic toxicity Target Organ Effects May cause adverse liver effects. kidney, liver.

Numerical measures of toxicity - Product Information

The following values are calculated based on chapter 3.1 of the GHS document .
ATEmix (oral) 79412 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

Very toxic to aquatic life with long lasting effects

17% of the mixture consists of component(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Crustacea
Dalbavancin 171500-79-1	Aspergillus niger (Fungus) MIC > 1000 mg/L Trichoderma viride (Fungus) MIC > 770 mg/L Clostridium perfringens (Bacterium) MIC 0.01 mg/L Bacillus subtilis (Bacterium) MIC 0.06 mg/L	>5.7 mg/L Rainbw Trout Nostoc sp. (Freshwater Cyanobacteria) MIC 3.1 mg/L	>4.3 mg/L Daphnia Magna

Other adverse effects No information available

13. DISPOSAL CONSIDERATIONS

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

Note: This material may be eligible for small quantity exemptions based on the quantity of material to be shipped.

DOT

Proper shipping name Consumer commodity
Hazard Class ORM-D
Special Provisions 222

Description	Environmentally hazardous substances, solid, n.o.s., ORM-D
TDG	
UN/ID No.	UN3077
Proper shipping name	Environmentally hazardous substances, solid, n.o.s.
Hazard Class	9
Packing Group	III
Description	UN3077, Environmentally hazardous substances, solid, n.o.s., 9, III
ICAO (air)	
UN/ID No.	UN3077
Proper shipping name	Environmentally hazardous substances, solid, n.o.s.
Hazard Class	9
Packing Group	III
Special Provisions	A158, A97, A179, A197
Description	UN3077, Environmentally hazardous substances, solid, n.o.s., 9, III
IATA	
UN/ID No.	UN3077
Proper shipping name	Environmentally hazardous substances, solid, n.o.s.
Hazard Class	9
Packing Group	III
ERG Code	9L
Special Provisions	A158, A179, A97, A197
Description	UN3077, Environmentally hazardous substances, solid, n.o.s., 9, III
IMDG	
UN/ID No.	UN3077
Proper shipping name	Environmentally hazardous substances, solid, n.o.s.
Hazard Class	9
Packing Group	III
EmS-No.	F-A, S-F
Special Provisions	274, 335, 966, 967, 969
Description	UN3077, Environmentally hazardous substances, solid, n.o.s., 9, III
ADR	
UN/ID No.	UN3077
Proper shipping name	Environmentally hazardous substances, solid, n.o.s.
Hazard Class	9
Packing Group	II
Classification code	M7
Tunnel restriction code	(E)
Special Provisions	274, 335, 601, 375
Description	UN3077, Environmentally hazardous substances, solid, n.o.s., 9, III, (E)
Labels	9
ADN	
UN/ID No.	UN3077
Proper shipping name	Environmentally hazardous substances, solid, n.o.s.
Hazard Class	9
Packing Group	III
Classification code	M7
Special Provisions	274, 335, 601
Description	UN3077, Environmentally hazardous substances, solid, n.o.s., 9, III
Hazard label(s)	9
Limited quantity (LQ)	5 kg

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

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

US State Regulations**California Proposition 65**

This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know Regulations**16. OTHER INFORMATION**

Revision Date 02-Oct-2018
Revision Note No information available

Disclaimer

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a 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.

End of Safety Data Sheet