MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
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1-212-573-2222

Pfizer Ltd
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Dalbavancin for Injection, 250 mg and 500 mg

Trade Name: ZEVEN
Chemical Family: Glycopeptide
Intended Use: Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: White to off-white to pale yellow solid

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
Short Term: May produce slight eye irritation (based on components) .
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on kidneys, liver.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include nausea, diarrhea, and vomiting.

EU Indication of danger: Not classified

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Dalbavancin	171500-79-1	Not listed	Not Listed	66

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Mannitol	69-65-8	200-711-8	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	*
Sodium hydroxide	1310-73-2	215-185-5	C;R35	**

Additional Information: * Proprietary
** to adjust pH

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8).

Storage Conditions: Store as directed by product packaging. Do not freeze.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Dalbavancin

Pfizer OEL TWA-8 Hr:	50µg/m^3

Sodium hydroxide

ACGIH Ceiling Threshold Limit:	= 2 mg/m^3 Ceiling
Australia PEAK	= 2 mg/m^3 Peak
Austria OEL - MAKs	= 2 mg/m^3 MAK
Belgium OEL - TWA	= 2 mg/m^3 TWA
Bulgaria OEL - TWA	= 2.0 mg/m^3 TWA
Czech Republic OEL - TWA	= 1 mg/m^3 TWA
Finland OEL - TWA	= 2 mg/m^3 TWA
France OEL - TWA	= 2 mg/m^3 VME
Greece OEL - TWA	= 2 mg/m^3 TWA
Hungary OEL - TWA	= 2 mg/m^3 TWA
Latvia OEL - TWA	= 0.5 mg/m^3 TWA
OSHA - Final PELS - TWAs:	2 mg/m^3
Poland OEL - TWA	= 0.5 mg/m^3 NDS
Slovakia OEL - TWA	= 2 mg/m^3 TWA
Slovenia OEL - TWA	= 2 mg/m^3 TWA
Sweden OEL - TWAs	= 1 mg/m^3 LLV

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Solid	**Color:**	White to off-white to slightly yellow
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Mannitol
Rat Oral LD 50 13500 mg/kg
Mouse Oral LD 50 22 g/kg

Dalbavancin
Rat Oral LD50 > 2 g/kg
Rat Intravenous LD50 186-205 g/kg

Sodium hydroxide
Mouse IP LD50 40 mg/kg
Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Dalbavancin
Eye Irritation Rabbit Minimal
Skin Irritation Rabbit Non-irritating
Skin Sensitization - M & K Guinea Pig Negative

Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Dalbavancin
3 Month(s) Rat Intravenous 5 mg/kg/day NOAEL Liver
3 Month(s) Dog Intravenous 5 mg/kg/day NOAEL Kidney, Liver

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Dalbavancin
Fertility and Embryonic Development Rat Intravenous 15 mg/kg/day NOEL Fertility
Embryo / Fetal Development Rat Intravenous 15 mg/kg/day NOAEL Maternal Toxicity, Paternal toxicity, Developmental toxicity
Embryo / Fetal Development Rabbit Intravenous 15 mg/kg/day NOEL Maternal Toxicity, Not Teratogenic
Peri-/Postnatal Development Rat Intravenous 15 mg/kg/day NOEL Maternal Toxicity, Fetotoxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Dalbavancin
In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative
In Vivo Micronucleus Mouse Bone Marrow Negative
Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Dalbavancin
Rainbow Trout OECD LC50 96 Hours > 5.7 mg/L
Microcystis aeruginosa (Blue-green Alga) OECD ErC50 96 Hours 0.054 mg/L
Daphnia magna OECD EC-50 48 Hours > 4.3 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Bacterial Inhibition: (Species, Method, End Point, Duration, Result)

Dalbavancin
Aspergillus niger (Fungus) MIC > 1000 mg/L
Trichoderma viride (Fungus) MIC > 770 mg/L
Clostridium perfingens (Bacterium) MIC 0.01 mg/L
Bacillus subtilis (Bacterium) MIC0.06 mg/L
Nostoc sp. (Freshwater Cyanobacteria) MIC 3.1 mg/L

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Mannitol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-711-8

Water for injection

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ = 454 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R35 - Causes severe burns.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 8 - Exposure Controls / Personal Protection.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet