BIOLOGICAL E. LIMITED

SDS: Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION

Common Name:	Daptomycin for Injection
Synonyms:	NA
Product use:	Antibacterial agent
Manufacturing site:	Biological E. Limited, Plot No: 4, Sy. No 542/P, Biotech Park, Phase-II, Kolthur Village-500078, Shameerpet Mandal, Medchal District, Telangana state, India.
Manufacturer Contact Details:	
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2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture GHS - Classification Specific target organ systemic toxicity (repeated exposure): Category 2

US OSHA Specific - Classification Physical Hazard: Combustible Dust

Label Elements Signal Word: Warning Hazard Statements:

H373 - May cause damage to organs through prolonged or repeated exposure May form combustible dust concentrations in air

Precautionary Statements:

P260 - Do not breathe dust/fume/gas/mist/vapors/spray

P314 - Get medical attention/advice if you feel unwell

P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards An Occupational Exposure Value has been established for this substance (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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

Component(s):

Chemical name	CAS-No.	GHS Classification	Concentration
Sodium hydroxide	1310-73-2	Skin Corr.1A (H314)	To adjust pH
Daptomycin	103060-53-3	STOT SE 2 (H373)	100 %

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

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

Advice for Fire-Fighters: During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

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.

Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe 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). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water

and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging. Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

Sodium hydroxide

ACGIH Ceiling Threshold Limit: 2 mg/m^3

Australia PEAK:	2 mg/m^3
Austria OEL – MAKs:	2 mg/m^3
Bulgaria OEL – TWA:	2.0 mg/m^3
Czech Republic OEL – TWA:	1 mg/m^3
Estonia OEL – TWA:	1 mg/m^3
France OEL – TWA:	2 mg/m^3
Greece OEL – TWA:	2 mg/m^3
Hungary OEL – TWA:	2 mg/m^3
Japan - OELs – Ceilings:	2 mg/m^3
Latvia OEL – TWA:	0.5 mg/m^3
OSHA - Final PELS - TWAs:	2 mg/m^3
Poland OEL – TWA:	0.5 mg/m^3
Slovakia OEL – TWA:	2 mg/m^3
Slovenia OEL – TWA:	2 mg/m^3
Sweden OEL – TWAs:	1 mg/m^3
Switzerland OEL -TWAs:	2 mg/m^3

Daptomycin

Occupational Exposure Band (OEB): OEB 2 (control exposure to the range of 100ug/m3 to < 1000ug/m3)

Exposure Controls

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:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: Pale yellow to light brown, lyophilized cake or powder
Odor	: Odorless.

Solubility	: Freely soluble in water, the solubility is 1 g/mL at 25^0C; Freely soluble in 0.1 mol/L NaOH; Insoluble in isopropanol, ethyl acetate, chloroform and acetonitrile
Density	: No information found.
pH	: 4.5 – 5.0

Melting/Freezing Point (°C): 215

Boiling Point (°C): No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Sodium hydroxide: No data available

Daptomycin: No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammablity:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable if stored in accordance with information listed on the product insert.

Possibility of hazardous reactions:

Oxidizing Properties: No data available

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

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects Short Term:

Accidental ingestion may cause effects similar to those seen in clinical use.

Known Clinical Effects: Adverse effects associated with therapeutic use include headache, allergic skin rash, liver effects, effects on musculoskeletal system, muscle pain, muscle weakness neuromuscular effects. Ingestion of this material may cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain.

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

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Daptomycin

Rat Oral Minimum Lethal Dose > 2000 mg/kg

Rat Dermal Minimum Lethal Dose > 200mg/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)

Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

Daptomycin

Skin Irritation Rabbit Slight

Eye Irritation Rabbit Slight

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

Daptomycin

1 Month(s) Rat Intravenous10 mg/kg/day LOAEL Skeletal muscle, Kidney

3 Month(s) Rat Intravenous 1 mg/kg/day LOAEL Skeletal muscle, Kidney

6 Month(s) Rat Intravenous 2 mg/kg/day LOAEL Kidney, Skeletal muscle, Bone Marrow 1 Month(s) Dog Intravenous 10 mg/kg/day LOAEL Bone Marrow, Skeletal muscle, Peripheral nervous system

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Daptomycin

Reproductive & Fertility Rat Intravenous150 mg/kg/day NOAEL Negative

Embryo / Fetal Development Rat Intravenous 75 mg/kg/day NOAEL Negative, Not Teratogenic

Embryo / Fetal Development Rabbit Intravenous 75 mg/kg/day NOAEL Negative, Not Teratogenic

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

Daptomycin

Bacterial Mutagenicity (Ames) Salmonella , E. coli Negative

Mammalian Cell Mutagenicity Not specified Negative

Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative

In Vivo Micronucleus Mouse Negative

In Vivo Sister Chromatid Exchange Hamster Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated.

Toxicity:

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

Sodium hydroxide

CERCLA/SARA 313 Emission reporting: Not Listed

CERCLA/SARA Hazardous Substances: 1000lb

and their Reportable Quantities:454 kg

California Proposition 65: Not Listed

Inventory - United States TSCA - Sect. 8(b): Present

Australia (AICS): Present

Standard for the Uniform Scheduling: Schedule 5

for Drugs and Poisons: Schedule 6

EU EINECS/ELINCS List: 215-185-5

Daptomycin

CERCLA/SARA 313 Emission reporting: Not Listed

California Proposition 65: Not Listed

Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4

EU EINECS/ELINCS List: Not Listed

16. OTHER INFORMATION

Disclaimer: Biological E. Limited provides the information without warranty and 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 excise 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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