



Omegacin Injectable

Preparation Date 08-Feb-2007

Revision Date 29-Jan-2008

Revision Number 1

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Omegacin Injectable
Common Name Not available
Chemical Name Not applicable
Synonyms Biapenem, CL-186815, L-627, LJC-10627
Product Use Pharmaceutical product
Classification Beta-lactam Antibiotic

Supplier Wyeth
P.O. Box 8299
Philadelphia, PA 19101 USA.
Telephone: 1-610-688-4400

Emergency Telephone Number Chemtrec USA, Puerto Rico, Canada 1-800-424-9300
Chemtrec International 1-703-527-3887

2. HAZARDS IDENTIFICATION

Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance Pharmaceutical powder **Physical State** Solid **Odor** Not available

Potential Physical Hazards Powders and solids are presumed to be combustible.

Potential Health Effects

Eyes May cause eye irritation.
Skin May cause skin irritation.
Inhalation May cause irritation of respiratory tract.
Ingestion Not available
Other Hypersensitivity (anaphylactic/anaphylactoid) reactions (including shock) have been reported in patients receiving therapy with penicillins. Individuals with a history of penicillin hypersensitivity or a history of sensitivity to multiple allergens should avoid contact. The most common effects may include pseudomembranous colitis, bleeding disorders, neuromuscular excitability, convulsions, joint pain, fever, hives or itching, liver toxicity, inflammation of the kidney, skin rash, decrease in the number of white blood cells, mental disturbances, and seizures.

May cause harm to breastfed babies.

Therapeutic Target Organ(s) None.

Not listed by OSHA, NTP or IARC.

Potential Environmental Effects There is no known ecological information for this product.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Biapenem	120410-24-4	300 mg/vial
Inactive Ingredients	Not applicable	Remainder

4. FIRST AID MEASURES

Eye Contact	In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.
Skin Contact	Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
Inhalation	Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.
Ingestion	If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Flammable Properties	Presumed to be a combustible particulate solid.
Extinguishing Media	
Suitable Extinguishing Media	Use water spray, foam, dry chemical or carbon dioxide.
Unsuitable Extinguishing Media	Do NOT use water jet.
Fire Fighting	Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.
Hazardous Combustion Products	Carbon oxides, nitrogen oxides.
Protective Equipment and Precautions for Firefighters	In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Refer to protective measures listed in Sections 7 and 8.
Environmental Precautions	Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.
Methods for Containment	Not available
Methods for Cleaning up	Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

7. HANDLING AND STORAGE

Handling	For personal protection see Section 8. Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.
Storage	No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name Biapenem	Exposure Guideline 3000 mcg/m ³
Engineering Controls	Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated.
Personal Protective Equipment	
Eye/face Protection	Provide eye protection based on risk assessment.
Skin Protection	Wear nitrile or latex gloves. Wear protective garment.
Respiratory Protection	Base respirator selection on a risk assessment.
General Hygiene Considerations	When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.
Other	Limit access to only personnel trained in the safe handling of this material. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Pharmaceutical powder	Physical State	Solid
Color	White	Odor	Not available
Odor Threshold	Not available		
pH	4.8 - 5.3		
Specific Gravity	Not applicable	Water Solubility	Soluble in water
Solubility	Not applicable	Evaporation Rate	Not applicable
Partition Coefficient (n-octanol/water)	Not available	Vapor Pressure	Not applicable
Boiling Point	Not applicable	Autoignition Temperature	Not applicable
Flash Point	Not available	Method	None
Melting Point	Not available		
Flammability Limits in Air	Upper Not applicable	Lower	Not applicable
Explosion Limits	Upper Not applicable	Lower	Not applicable

10. STABILITY AND REACTIVITY

Chemical Stability	Stable at room temperature.
Conditions to Avoid	No data available
Materials to Avoid	No materials to be especially mentioned.
Hazardous Decomposition Products	None under normal use.
Possibility of Hazardous Reactions	None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Biapenem

LD50 Oral	>2000 mg/kg rats (IV) >1000 mg/kg dogs (IV)
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	Not a dermal sensitizer in guinea pigs.

Multiple Dose Toxicity

Biapenem

No Toxicologic Effect Dose/Species/Study Length:	The no toxicological effect level (NTEL) in rat studies was 300 mg/kg/day and in the dog studies 20 mg/kg/day. In dogs, death due to intestinal toxicity, emesis, salivation, mucous feces, immobilization, paleness, hypothermia, slight reduction of body weight and food consumption, red discoloration of the large intestine, and slight histopathological change of renal tubules were observed. The changes, including signs of toxicity, were reversible in rats and dogs, except for cecum enlargement of rats.
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Maximum Tolerated Dose (MTD), Oral

Biapenem

Carcinogenicity	No data available
Genetic Toxicity	No evidence of mutagenicity was observed in a battery of <i>in vitro</i> and <i>in vivo</i> assays.
Reproductive Toxicity	Studies in rats were found to have no effect on fertility.
Developmental Toxicity	No morphological anomalies were observed in segment II studies in rats and rabbits.

Biapenem

Target Organ(s) of Toxicity	No data available
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12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information Not available

Ecotoxicity Not available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of in accordance with local and national regulations. Waste is inactivated by treatment with sodium hypochlorite solution.

14. TRANSPORT INFORMATION

Transport Information This material is not classified as hazardous for transport.

U.S. Department of Transport (DOT)	Not regulated
Canadian Transport of Dangerous Goods (TDG)	Not regulated
International Civil Aviation Organization (ICAO)	Not regulated
International Air Transport Association (IATA)	Not regulated
International Maritime Dangerous Goods (IMDG)/International Maritime Organization (IMO)	Not regulated
Transport of Dangerous Goods by Rail (RID)	Not regulated
Transport of Dangerous Goods by Road (ADR)	Not regulated
Transportation of Dangerous Goods via Inland Waterways (ADN)	Not regulated

15. REGULATORY INFORMATION

USA

Federal Regulations

OSHA Regulatory Status

This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

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 40n of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazardous Categorization

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

This product does not contain any HAPs.

State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

Canada

Not classified

WHMIS Hazard Class

Non-controlled

European Union

In accordance with EC directives or respective national laws, the product does not need to be classified nor labeled.

16. OTHER INFORMATION

Prepared By	Wyeth Department of Environment, Health & Safety
Format	This MSDS was prepared in accordance with ANSI Z400.1-2004.
List of References	See Patient Package Insert for more information.
Revision Summary	Administrative

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