

## 1 IDENTIFICATION OF THE SUBSTANCE OR MIXTURE AND OF THE SUPPLIER

**Product Name:** ERTAPENEM FOR INJECTION

**Distributed By:** WG Critical Care, LLC.  
120 Route 17 North  
Suite 115  
Paramus, NJ 07652 USA

**Customer Service Phone Number:** 1-888-493-0861  
**Emergency Phone Number:** 1-866-562-4708 (ProPharma)

**Product Use:** Pharmaceutical  
**Product Type:** Antibacterial  
**Container Information:** GLASS VIAL

## 2 HAZARDS IDENTIFICATION

**Classification of Substance or Mixture:** Combustible Dust  
Respiratory Sensitivity 1 H334  
**Hazard Pictogram:**



**Signal Word:** Danger

**Hazard Statements:** H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled

H317: May cause an allergic skin reaction

H314: Causes severe skin burns and eye damage

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**Precautionary Statements:** P261 - Avoid breathing dust/fume/gas/mist/vapors/spray P284 - [In case of inadequate ventilation] wear respiratory protection

P304+P341 - If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing

P342+P311 - If experiencing respiratory symptoms: Call a poison center/doctor/...

P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

**Other Hazards:** Serious and sometimes fatal hypersensitivity reactions (anaphylactic) have been reported in patients receiving beta lactam antibiotic therapy. These reactions occur more in individuals with a history of sensitivity to multiple allergens (2).  
Cross sensitivity: People sensitive to cephalosporins or to penicillins and penicillin derivatives, or to penicillamine may also be sensitive to this material.  
If heated the substance may emit toxic fumes (for more information see section 5.2).

**Unknown acute toxicity:** Not applicable

### 3 COMPOSITION / INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

<u>Ingredient</u>	<u>Weight %</u>	<u>CAS No.</u>
Ertapenem	≥70 - < 90	153773-82-1

In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

### 4 FIRST AID MEASURES

Description of first aid measures

**GENERAL:** In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

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**INHALATION:** Move to fresh air and monitoring breathing. If breathing becomes difficult or stops, give oxygen and activate the emergency.

**EYES:** Wash out with fresh running water for at least 15 minutes. Ensure complete irrigation of the eyes by keeping eyelids well open. Consult a doctor.

**SKIN:** Remove contaminated clothing and replace them with clean and dry ones. Wash the exposed skin area with soap and water. Seek medical attention in case of irritation.

**INGESTION:** Do not induce vomiting. Immediately rinse mouth with water and call the Poison Control Centre. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-unconscious.

**Acute and Delayed Effects:** Some individuals may experience severe allergic reactions such as asthma and anaphylactic shock. Possible hypersensitivity.

**Indication of any immediate medical attention and special treatment needed:** No additional information available

## 5 FIRE FIGHTING MEASURES

**Extinguishing Media:** Use water spray, alcohol resistant foam, carbon dioxide or dry chemical

**Special hazards arising from the substance or mixture:** During combustion toxic gases can form such as carbon oxides (COX), nitrogen oxides (NOX) and sulfur compounds.

**Advice for Fire-Fighters:** Do not enter fire area without proper protective equipment, including respiratory protection

## 6 ACCIDENTAL RELEASE MEASURE

**Personal precautions, protective equipment and emergency procedures** Avoid inhalation and contact with eyes and skin. Alert Emergency Responders and tell them location and nature of hazard.

Avoid inhalation and contact with eyes and skin. Wear approved respiratory protection, chemically compatible gloves and protective clothing and safety glasses.

### MINOR SPILLS

Wash the affected area immediately.  
 Use dry clean up procedures and avoid generating dust.  
 Sweep up or vacuum up.  
 Place spilled material in clean, dry, suitable, labeled container.

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**MAJOR SPILLS**

Control personal contact by using protective equipment.  
Prevent spillage from entering drains, sewers or water courses.  
Avoid generating dust.

Recover product wherever possible.

Put residues in labeled plastic bags or other containers for disposal.

If contamination of drains or waterways occurs, advise emergency services

**Environmental precautions**

Prevent entry to sewers and public water

**Methods and material for containment and cleaning up**

Stop the flow of material, if this is without risk.

Methods for cleaning up

Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.

**7 HANDLING AND STORAGE**

**Precautions for safe handling**

Do not breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.

**Conditions for safe storage, including any incompatibilities**

Do not store lyophilized powder above 25°C (77°F).

**8 EXPOSURE CONTROLS / PERSONAL PROTECTION**

**CONTROL PARAMETERS:**

<u>CAS No.</u>	<u>Ingredient</u>	<u>Value</u>	<u>Control Parameters</u>
153773 – 82- 1	Ertapenem Sodium	TWA	800ug / m <sup>3</sup>

**EXPOSURE CONTROLS**

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**Appropriate Engineering Controls:** Analytical surveys are conducted to assess the concentration of dust in the work environment.

**Personal Protection:**

- Eye protection:  
Must wear proper eye protection.
- Skin protection:  
Tyvek coverall, safety shoes, waterproof gloves forearm in latex (length 320 mm and thickness 0.4 mm) or neoprene gloves (length 300 mm and thickness 0.75 mm).
- Respiratory system protection:  
Filter system FFP2.

Attention: for the choice of the material, take into consideration the possible individual allergic reactions.

**Environmental Exposure Controls:** Prevent release to drains and waterways.

## 9 PHYSICAL AND CHEMICAL PROPERTIES

<b>PHYSICAL STATE:</b>	Solid lyophilized powder	<b>APPEARANCE:</b>	White to light yellow
<b>UPPER FLAMMABILITY LIMIT:</b>	Not determined	<b>LOWER FLAMMABILITY LIMIT:</b>	Not determined
<b>EXPLOSIVE LIMITS:</b>	Not determined	<b>ODOR:</b>	Not determined
<b>VAPOR PRESSURE:</b>	Not determined	<b>ODOR THRESHOLD:</b>	Not determined
<b>VAPOR DENSITY:</b>	Not determined	<b>pH:</b>	7-8
<b>RELATIVE DENSITY:</b>	Not determined	<b>MELTING POINT:</b>	Not determined
<b>FREEZING POINT:</b>	Not determined	<b>SOLUBILITY:</b>	Not determined
<b>INITIAL BOILING POINT:</b>	Not determined	<b>BOILING RANGE:</b>	Not determined
<b>FLASH POINT:</b>	Not determined	<b>EVAPORATION RATE:</b>	Not determined
<b>FLAMMABILITY:</b>	Not determined	<b>PARTITION COEFFICIENT (N-OCTANOL / WATER)</b>	Not determined
<b>AUTO-IGNITION TEMPERATURE:</b>	Not determined	<b>DECOMPOSITION TEMPERATURE:</b>	Not determined
<b>VISCOSITY:</b>	Not determined		

## 10 STABILITY AND REACTIVITY

**Reactivity:** No known reactivity hazard under normal conditions. See Section 7 for details.

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**Chemical Stability** Stable under normal circumstances. See section 7

**Possibility of Hazardous reactions:** No data available.

**Conditions to avoid:** Protect from moisture. Store in a dry place.  
Avoid accumulation of electrostatic charge. Connect to the circuit ground. Keep away from open flames, heat and direct lighting.

**Incompatible Materials:** No data available

**Hazardous decomposition products:** Regarding the production of combustion product, see section 5

## 11 TOXICOLOGICAL INFORMATION

### ACUTE TOXICITY

COMPONENT	Oral LD50 Mouse	IV LD50 Mouse	IV LD50 Rat		
Ertapenem for Injection	>500mg/kg	>700mg/kg	>700mg/kg		

Note: As a result of the physical presentation of the product, the risk to health is expected to be very low under normal conditions of handling and use. The following health hazard assessment is based on a consideration of the composition of this product.

**Serious Eye Damage / Irritation:** Not determined

**Respiratory or Skin Sensitization:** May cause sensitization by inhalation and skin contact

**Germ Cell Mutagenicity:** Not determined

**Carcinogenicity:** No animal carcinogenicity studies have been conducted with Ertapenem

**Reproductive Toxicity:** There are no adequate and well-controlled studies regarding the effect of the use of Ertapenem on fertility in men and women. Preclinical studies do not indicate direct or indirect dangerous effects on fertility.

**STOT Single Exposure:** Not determined

**STOT Repeated Exposure:** Not determined

**Aspiration Hazard:** Not determined



**TOXICOKINETICS, METABOLISM AND DISTRIBUTION**

**Absorption:** Not determined

**Distribution:** There is no accumulation of Ertapenem in adults after multiple intravenous infusions of doses ranging from 0.5 to 2 g per day. Ertapenem is extensively bound to human plasma proteins. In healthy young adults (from 25 to 45 years of age), binding of Ertapenem to proteins decreases, with increasing plasma concentrations, from about 95% of drug bound to an indicative plasma concentration <50 µg/l to about 92% of drug bound to a concentration of drug bound to a plasma concentration of about 155 µg/l (average concentration reached at the end of the intravenous infusion of 1 g).

The volume of distribution (Vdss) of Ertapenem in adults is about 8 liters (0,11 liters / kg) and about 0.2 liters / kg in pediatric patients aged between 3 months and 12 years and about 0, 16 liters / kg in pediatric patients aged from 13 to 17 years.

**Metabolism:** In healthy young adults (from 23 to 49 years of age), after intravenous infusion of 1 g of radiolabelled Ertapenem, plasma radioactivity consists predominantly (94%) of Ertapenem. The main metabolite of Ertapenem is the open-loop derivative formed by the hydrolysis of the beta-lactam ring mediated by dihydropeptidase -I.

In vitro studies on human liver microsomes indicate that Ertapenem does not inhibit metabolism mediated by the six main isoforms of CYP: 1A2, 2C9, 2C19, 2D6, 2E1 and 3A4.

**Excretion:** Following intravenous administration of a dose of 1 g of radiolabelled Ertapenem to healthy young adults (from 23 to 49 years of age), approximately 80% of the drug is found in urine and 10% in feces. Of the 80% found in urine, about 38% is excreted as unchanged Ertapenem and about 37% as an open-loop metabolite. Ertapenem is excreted in breast milk.

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## 12 ECOLOGICAL INFORMATION

### Toxicity

<b>TOXICITY:</b>	Not determined
<b>PERSISTENCE AND DEGRADABILITY:</b>	Result: rapidly degradable Biodegradation: 50 % Exposure time: 3.4 hrs
<b>BIOACCUMULATIVE POTENTIAL:</b>	Degradation half life (DT50): 15.3 days Log Pow -2.22
<b>MOBILITY IN SOIL:</b>	Not determined
<b>RESULTS OF PBT AND vPvB ASSESSMENT:</b>	Not determined
<b>OTHER ADVERSE EFFECTS:</b>	Not determined

## 13 DISPOSAL CONSIDERATIONS

<b>Waste treatment methods</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Contaminated packaging:</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

## 14 TRANSPORT INFORMATION

### REGULATORY ORGANIZATIONS:

**DOT:** Not Regulated

**IMDG:** Not regulated

**ICAO / IATA:** Not Regulated

**IMO:** Not Regulated

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## 15 REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible WG Critical Care use. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your city / state / country.

### US Regulations

TSCA – No

CERCLA-No

SARA 302 – This material does not contain any components with a section 302 EHS TPQ.

SARA 313 – This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

OSHA Substance Specific - No

California Prop 65 – This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects

## 16 OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PUROPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

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**END OF SAFETY DATA SHEET**

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