

# SAFETY DATA SHEET

**PRODUCT NAME:** INVANZ® (ERTAPENEM FOR INJECTION)

**Page:** 1/7

**Revision** 3-Jan-2008

## 1. Product and Company Identification

Manufactured/Supplied by MERCK & CO., INC.  
One Merck Drive  
Whitehouse Station, NJ 08889-0100  
(908) 423-1000

Emergency Telephone Number: 1-732-594-5555

Label Name INVANZ® (ERTAPENEM FOR INJECTION)  
Chemical Name **Ertapenem Sodium:**  
[4R-[3(3S\*,5S\*),4alpha,5beta,6beta(R\*)]]-3-[[5-[[[(3-carboxyphenyl)amino]carbonyl]-3-pyrrolidinyl]thio]-6-(1-hydroxyethyl)-4-methyl-7-oxo-1-azabicyclo[3.2.0]hept-2-ene-2-carboxylic acid monosodium salt

Synonyms Ertapenem sodium; Ertapenem for Injection for Intravenous or Intramuscular Use.

Material Product Number 3843  
**NDC:** 0006-3843-71 in trays of 10 vials  
**NDC:** 0006-3843-45 in trays of 25 vials.

Intended Use Finished pharmaceutical product.

## 2. Composition/Information on Ingredients

<u>Component</u>	<u>Molecular Formula</u>	<u>Molecular weight</u>	<u>CAS Number</u>	<u>Percent (%)</u>
ERTAPENEM SODIUM	C <sub>22</sub> H <sub>24</sub> N <sub>3</sub> O <sub>7</sub> SNa	497.5	153832-38-3	85.6
SODIUM BICARBONATE	CHNaO <sub>3</sub>	84.01	144-55-8	14.4

EC Label Exempt from the EU Dangerous Substances Directive.

## 3. Hazards Identification

Appearance Sterile, white to off-white, freeze-dried powder. Reconstituted solutions range from colorless to pale yellow.

Label Text CAUTION!  
FINISHED PHARMACEUTICAL PRODUCT  
No specific hazard with intact vials.

Emergency Overview Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

Potential Health Effects See Section 11 for detailed information.

\*\*\* Continued on next page \*\*\*

#### 4. First Aid Measures

<u>Eye Contact</u>	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.
<u>Skin Contact</u>	Wash with soap and water. Get medical attention if irritation develops.
<u>Inhalation</u>	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear.
<u>Ingestion</u>	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention if symptoms appear.
<u>Notes to physician</u>	<p>This product has the potential to cause serious hypersensitivity reactions (including anaphylaxis) in individuals that are allergic to other beta-lactam antibiotics.</p> <p>For additional guidance refer to the current prescribing information or the local poison control center.</p>

#### 5. Fire Fighting Measures

<u>Flash Point</u>	Not applicable
<u>Flammable Limits (% in air)</u>	Not applicable
<u>Autoignition Temperature</u>	Not available.
<u>Oxidizing Properties</u>	Not available.
<u>Combustibility Information</u>	Contents of vials are combustible.
<u>Dust Explosivity Information</u>	Vial contents represent a moderate dust explosion hazard.
<u>Shock Sensitivity</u>	No.
<u>Fire/Explosion Hazards</u>	None known.
<u>Special Fire Procedures</u>	Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.
<u>Extinguishing Media</u>	In case of fire, use water spray (fog), foam or dry chemicals.
<u>Hazardous Decomposition Products</u>	These products are carbon oxides, nitrogen oxides, sulfur oxides. Some metallic oxides.

#### 6. Accidental Release Measures

<u>Personal Precautions</u>	<b>See Section 8 for Personal Protective Equipment.</b> Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all fire fighting procedures (Section 5).
<u>Methods for cleaning up</u>	If emergency personnel are unavailable vacuum or carefully scoop up spilled materials and place in an appropriate container for disposal. Avoid creating dusty conditions and prevent wind dispersal. Minimize contact of spilled material with soils to prevent runoff to surface waterways. <b>See Section 13 for Waste Disposal Information.</b>

## 7. Handling and Storage

### Handling

Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

### Storage

Keep container tightly closed. Keep container in a cool, well-ventilated area. Do not store lyophilized powder above 25°C (77°F).

## 8. Exposure Controls/Personal Protection

### Exposure Guidelines

<u>Component</u>	<u>OSHA Permissible Exposure Limit (PEL)</u>	<u>ACGIH Threshold Limit Value (TLV)</u>	<u>Merck Exposure Control Limit (ECL) or PB-ECL Category</u>
ERTAPENEM SODIUM	Not established	Not established	1 mg/m <sup>3</sup> (TWA)
SODIUM BICARBONATE	Not established	Not established	Not established

ADI = 10 mg/day for ECL only

Wipe Test Criteria = Not required

### Engineering Controls

None required with normal handling of finished product.

Use feasible engineering controls to minimize exposure to compound.

### Personal Protective Equipment

#### Eye/Face Protection

None required with normal handling of finished product.

Safety glasses with side shields. Where the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

#### Skin Protection

None required with normal handling of finished product.

Disposable chemical resistant gloves.

#### Respiratory Protection

None required with normal handling of finished product.

Use an appropriate approved air-purifying respirator equipped with HEPA cartridges/canisters where there is the potential for exceeding established occupational exposure limits or occupational exposure bands. When handling a compound in solution, a cartridge/canister appropriate for the solution may also be needed.

Use a positive pressure, air-supplied, pressure demand tight fitting respirator (e.g., SCBA or airline equipped with emergency escape bottle) where there is a potential for uncontrolled releases in excess of the respirator's capabilities, where exposure levels are unknown or where air-purifying respirators may not provide adequate protection.

Additional Protective Equipment

None required with normal handling of finished product.

Work uniform or laboratory coat.

**9. Physical and Chemical Properties**Appearance

Sterile, white to off-white, freeze-dried powder. Reconstituted solutions range from colorless to pale yellow.

Odor/Threshold Limit**ERTAPENEM SODIUM:** Odorless.  
**SODIUM BICARBONATE:** Odorless.pH

Not applicable

Boiling Point

Not applicable

Melting Point**ERTAPENEM SODIUM:** 192°C (377.6°F)Flash point

Not applicable

Flammable Limits (% in air)

Not applicable

Autoignition Temperature

Not available.

Solubility**ERTAPENEM SODIUM:** Easily soluble in cold water (>500 mg/ml).Partition Coefficient**ERTAPENEM SODIUM:** Log Kow: -2.22Specific Gravity

Not applicable

Vapor Density

Not applicable

Vapor Pressure

Not applicable

Volatility Component

0% (w/w).

**10. Stability and Reactivity**Stability**ERTAPENEM SODIUM:** Prolonged aging at temperatures above 40°C should be avoided. Tests show the material could very slowly generate heat and/or pressure if maintained above 40°C.Conditions to Avoid

Avoid storage temperatures greater than 25°C (77°F).

Incompatibility

Not applicable.

Hazardous Polymerization**ERTAPENEM SODIUM:** Will not occur.Hazardous Decomposition Products

These products are carbon oxides, nitrogen oxides, sulfur oxides. Some metallic oxides.

**11. Toxicological Information**Routes of EntryIngestion: No.  
Inhalation: Unlikely  
Skin Contact: No.Toxicity Data

<u>Component</u>	<u>Test</u>	<u>Species</u>	<u>Route</u>	<u>Result</u>
------------------	-------------	----------------	--------------	---------------

ERTAPENEM	LD50	Mouse	Oral	>500 mg/kg
SODIUM	LD50	Rat	I.V.	>700 mg/kg
	LD50	Mouse	I.V.	>2000 mg/kg
SODIUM BICARBONATE	LD50	Rat	Oral	4220 to 8000 mg/kg

Effects of Acute ExposureEye contact

Direct contact may cause irritation and redness.

Skin contact

None expected for the finished product based on data for ertapenem sodium.

Inhalation

Non-irritating to the respiratory system.

Ingestion

Practically non-toxic if swallowed.

Effects of Chronic Exposure

**ERTAPENEM SODIUM:** Carbapenem antibiotic for intravenous and intramuscular use. In repeat-dose intravenous toxicity studies there was a decrease in neutrophils observed in rats and very slight liver and kidney changes observed in monkeys. There were no adverse effects reported in developmental and reproductive toxicity studies except decreased fetal weights and incomplete bone growth at high dosages in mice. There was no evidence of genotoxicity.

In clinical studies the most common drug-related adverse experiences were diarrhea, infused vein complication, nausea, headache, vaginitis, phlebitis/thrombophlebitis and vomiting. Rarely, seizures have also been reported. The most common drug-related adverse laboratory findings included increased liver enzymes, serum alkaline phosphatase and platelet count.

Carcinogen Designation

Not listed as a carcinogen by OSHA, NTP or IARC.

Medical Conditions Aggravated by Overexposure:

Renal insufficiency, pre-existing allergy to other beta-lactam antibiotics. Carbapenems may reduce serum valproic acid concentrations resulting in a loss of seizure control.

**12. Ecological Information**Environmental Effects

Practically non-toxic to aquatic organisms.

**ERTAPENEM SODIUM:** Ertapenem sodium is minimally toxic to aquatic organisms. While the compound theoretically may have an impact on activated sludge organisms (ASRIT EC10 = 3.9 mg/L), the likely influx to sewage treatment plants will be well below this amount. Furthermore the compound decomposes fairly rapidly.

Ecotoxicity Data

<u>Component</u>	<u>Species</u>	<u>Period</u>	<u>Result</u>
ERTAPENEM SODIUM	<i>Daphnia magna</i> (LC50)	48 hours	>500 mg/L
	Fathead minnow (LC50)	96 hours	>1000 mg/L
	<i>S. Capricornutum</i> (EC50)	96 hours	545 mg/L
SODIUM BICARBONATE	Not available.	Not available.	Not available.

Environmental Fate

**ERTAPENEM SODIUM** Ertapenem sodium is highly soluble in water and has a log Kow = -2.22 indicating very low probability for binding to sludge, soil or sediment. QSAR also suggests low probability for bioaccumulation. Aqueous solutions of the compound decompose at a moderate rate ( $t_{1/2} = 4.73$  days).

**13. Disposal Considerations**Waste Disposal Information

Avoid contact of spilled material and runoff with soil and surface waterways. Dispose of or treat all spills residues including contaminated soils following all federal, state, or local regulations.

**14. Transport Information**Shipping DescriptionU.S. DOT

Not regulated.  
DRUGS OR MEDICINES, NOI  
Note: Maintain product temperature between 2-8°C.

IATA/ICAO

Not regulated  
Note: Maintain product temperature between 2-8°C.

IMO

Not regulated  
Note: Maintain product temperature between 2-8°C.

ADR/RID

Not regulated.  
Note: Maintain product temperature between 2-8°C.

**15. Regulatory Information**U.S. Federal Regulations

Not hazardous per OSHA Hazard Communication Standard criteria (29 CFR 1910.1200)

State Regulations

Not available

International Regulations

Exempt from the EU Dangerous Substances Directive.

**16. Other Information**

Revisions: Notes to Physician, Exposure Controls and Personal Protection, Medical Conditions Aggravated by Overexposure

Revision:

1/3/2008.

MSDS Coordinator:

1-908-423-7903  
Merck & Co., Inc.  
Two Merck Drive  
P.O. Box 200, WS2W-13  
Whitehouse Station, NJ 08889-0200  
U.S.A.

Disclaimer:

While this information and recommendations set forth are believed to be accurate as of the date hereof, MERCK & CO, INC. makes no warranty with respect hereto and disclaims all liability from reliance thereon.