# Ertapenem for Injection

Safety Data Sheet

According to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations
Date of Issue: 05/14/2025 Version: 1.0

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Product Form:** Mixture

**Product Name:** Ertapenem for Injection

### 1.2 Recommended Use and Restrictions on Use

**Use of the Substance/Mixture:** Carbapenem Antibiotic

No additional information available

### 1.3. Name, Address, and Telephone of the Responsible Party

WG Critical Care, LLC.120 Route 17 North, Suite 115
Paramus, NJ 07652 USA
+ 1-888-493-0861
wgccquality@wgcriticalcare.com
www.wgcriticalcare.com

### 1.4. Emergency Telephone Number

**Emergency Number** : +1-866-562-4708 (ProPharma)

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the Substance or Mixture

**GHS-US Classification**

| | |
|---|---|
| Skin corrosion/irritation, Category 2 | H315 |
| Serious eye damage/eye irritation, Category 1 | H318 |

### 2.2. Label Elements

**GHS-US Labeling**

**Hazard Pictograms (GHS-US)** :

GHS05

**Signal Word (GHS-US)** : Danger

**Hazard Statements (GHS-US)** : H315 - Causes skin irritation.
H318 - Causes serious eye damage.

**Precautionary Statements (GHS-US)** : P264 - Wash hands, forearms and face thoroughly after handling.
P280 - Wear protective gloves.
P302+P352 - If on skin: Wash with plenty of water.
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 - Immediately call a poison center or doctor.
P321 - Specific treatment (see Section 4 of this Safety Data Sheet on this label).
P332+P313 - If skin irritation occurs: Get medical advice or attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.

### 2.3 Hazards associated with known or reasonably anticipated uses

This product is a pharmaceutical product designed for administration to a patient by a qualified medical professional. No other uses are anticipated. A Process Hazard Analysis (PHA) or other hazard assessment for additional specific end uses should be performed to ensure that hazards are fully understood, and adequate safety measures are in place. See Section 10 for relevant reactivity and stability information.

### 2.4. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

### 2.5. Unknown Acute Toxicity (GHS-US)

No data available

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substance

Not applicable

### 3.2. Mixture

| Name | Synonyms | Product Identifier | % | GHS US classification |
|---|---|---|---|---|
| Ertapenem sodium | None | (CAS-No.) 153773-82-1 | 80 – 100 | Not classified. |
| Disodium carbonate | Sodium carbonate / Carbonic acid, disodium salt / Soda ash / Sodium carbonate (2:1) / Sodium carbonate, anhydrous / Carbonic acid sodium salt (1:2) / SODIUM CARBONATE / Sodium carbonate anhydrous | (CAS-No.) 497-19-8 | 10 – 20 | Eye Irrit. 2A, H319 |
| Sodium hydroxide | Caustic soda / Sodium hydroxide (Na(OH)) / SODIUM HYDROXIDE / LYE / Lye solution | (CAS-No.) 1310-73-2 | 1 – <5 | Met. Corr. 1, H290<br>Acute Tox. 4 (Oral), H302<br>Acute Tox. 4 (Dermal), H312<br>Skin Corr. 1A, H314<br>Eye Dam. 1, H318<br>Aquatic Acute 3, H402 |

Full text of H-phrases: see section 16

* The actual concentration of ingredient(s) is withheld as a trade secret in accordance with the 29 CFR 1910.1200. Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%),This mixture has a variable composition.

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of First-aid Measures

**First-aid Measures General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

**First-aid Measures After Inhalation:** Using proper respiratory protection, immediately move the exposed person to fresh air. Encourage exposed person to cough, spit out, and blow nose to remove dust. Obtain medical attention if breathing difficulty persists.

**First-aid Measures After Skin Contact:** Remove contaminated clothing. Wash immediately with plenty of soap and water. Obtain medical attention if irritation develops or persists.

**First-aid Measures After Eye Contact:** Immediately rinse with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

**First-aid Measures After Ingestion:** Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

### 4.2. Most Important Symptoms and Effects Both Acute and Delayed

**Symptoms/Injuries:** Causes serious eye damage. Causes skin irritation.

**Symptoms/Injuries After Inhalation:** Prolonged exposure may cause irritation.

**Symptoms/Injuries After Skin Contact:** Causes skin irritation.

**Symptoms/Injuries After Eye Contact:** Contact causes severe irritation with redness and swelling of the conjunctiva. Causes serious eye damage.

**Symptoms/Injuries After Ingestion:** Ingestion may cause adverse effects.

**Chronic Symptoms:** None expected under normal conditions of use.

### 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand. Treat needlestick exposures symptomatically to include monitoring for anaphylaxis.

## SECTION 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Water spray, fog, carbon dioxide ($CO_2$), alcohol-resistant foam, or dry chemical.

**Unsuitable Extinguishing Media:** Do not use a heavy water stream. Use of heavy stream of water may spread fire.

### 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** Not considered flammable but may burn at high temperatures. Product is not a dust as supplied; however, product dusts may be combustible.

**Explosion Hazard:** Product is not a dust as supplied; however, product dusts may be combustible.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

### 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire.

**Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Hazardous Combustion Products:** Oxides of carbon, nitrogen, sulfur and sodium.

**Other Information:** No additional information available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Avoid all contact with skin, eyes, or clothing. Avoid breathing dust. If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

#### 6.1.1. For Non-Emergency Personnel

**Protective Equipment:** Use appropriate personal protective equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

#### 6.1.2. For Emergency Personnel

**Protective Equipment:** Equip cleanup crew with proper protection.

**Emergency Procedures:** Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

### 6.2. Environmental Precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and Materials for Containment and Cleaning Up

**For Containment:** Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams.

**Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Recover the product by vacuuming, shoveling or sweeping. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

### 6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Additional Hazards When Processed:** Material may be biologically contaminated with pathogenic organisms during use.

**Precautions for Safe Handling:** Avoid contact with skin, eyes and clothing. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid breathing dust. Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program. In hospital and workplace settings, contaminated sharps are to be handled in accordance with established protocols.

**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

**Storage Conditions:** Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

**Incompatible Materials:** Strong acids, strong bases, strong oxidizers.

**Storage Temperature:** Do not freeze reconstituted product.

### 7.3. Specific End Use(s)

Carbapenem Antibiotic

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

| **Sodium hydroxide (1310-73-2)** | | |
|---|---|---|
| **USA ACGIH** | ACGIH OEL C | 2 mg/m³ |
| **USA NIOSH** | NIOSH REL C | 2 mg/m³ |
| **USA IDLH** | IDLH | 10 mg/m³ |
| **USA OSHA** | OSHA PEL TWA | 2 mg/m³ |

### 8.2. Exposure Controls

**Appropriate Engineering Controls** : Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

**Personal Protective Equipment** : Gloves. Protective clothing. Protective goggles or glasses.

| | | |
|---|---|---|
| **Materials for Protective Clothing** | : | Chemically resistant materials and fabrics. |
| **Hand Protection** | : | Wear protective gloves. |
| **Eye and Face Protection** | : | Chemical goggles or safety glasses. |
| **Skin and Body Protection** | : | Wear suitable protective clothing. |
| **Respiratory Protection** | : | If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection. |
| **Thermal Hazard Protection** | : | Not applicable. |
| **Environmental Exposure Controls** | : | Avoid unnecessary release into the environment. |
| **Other Information** | : | When using, do not eat, drink or smoke. |

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

| | | |
|---|---|---|
| **Physical State** | : | Solid |
| **Color** | : | White to light yellow solid, crystalline powder |
| **Odor** | : | No data available |
| **pH** | : | 7.0 – 8.0 [When reconstituted] |
| **Melting Point** | : | No data available |
| **Freezing Point** | : | No data available |
| **Boiling Point** | : | No data available |
| **Flash Point** | : | No data available |
| **Auto-ignition Temperature** | : | No data available |
| **Decomposition Temperature** | : | No data available |
| **Flammability (solid, gas)** | : | No data available |
| **Vapor Pressure** | : | No data available |
| **Relative Vapor Density at 20°C** | : | No data available |
| **Relative Density** | : | No data available |
| **Solubility** | : | Water: Soluble |
| **Partition Coefficient: N-Octanol/Water** | : | No data available |
| **Viscosity, Kinematic** | : | No data available |
| **Particle Size** | : | No data available |
| **Particle Size Distribution** | : | No data available |
| **Particle Shape** | : | No data available |
| **Particle Aspect Ratio** | : | No data available |
| **Particle Aggregation State** | : | No data available |
| **Particle Agglomeration State** | : | No data available |
| **Particle Specific Surface Area** | : | No data available |
| **Particle Dustiness** | : | No data available |
| **Explosive Properties** | : | Dust generated from processing may present a dust explosion hazard. |

### 9.2. Other Information

No additional information available

## SECTION 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

Hazardous reactions will not occur under normal conditions.

### 10.2. Chemical Stability

Stable under recommended handling and storage conditions (see section 7).

### 10.3. Possibility of Hazardous Reactions, Including those Associated with Foreseeable Emergencies

Hazardous polymerization will not occur. Under fire conditions, thermal decomposition products include the following: Oxides of carbon, nitrogen, sulfur and sodium.

### 10.4. Conditions to Avoid

Direct sunlight, extremely high or low temperatures, and incompatible materials. Avoid creating or spreading dust.

### 10.5. Incompatible Materials

Strong acids, strong bases, strong oxidizers.

### 10.6. Hazardous Decomposition Products

Thermal decomposition may produce: Oxides of carbon, nitrogen, sulfur and sodium.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on Toxicological Effects

**Likely Routes of Exposure:** Dermal, Ingestion, Inhalation, Eye contact

**Acute Toxicity (Oral):** Not classified.

**Acute Toxicity (Dermal):** Not classified.

**Acute Toxicity (Inhalation):** Not classified.

| **Disodium carbonate (497-19-8)** | |
|---|---|
| **LD50 Oral Rat** | 2800 mg/kg |
| **LD50 Dermal Rabbit** | > 2000 mg/kg (No deaths) |
| **LC50 Inhalation Rat** | 2300 mg/m³ (Exposure time: 2 h) |

| **Sodium hydroxide (1310-73-2)** | |
|---|---|
| **LD50 Oral Rat** | 325 mg/kg |
| **LD50 Dermal Rabbit** | 1350 mg/kg (Source: NLM_HSDB) |

**Skin Corrosion/Irritation:** Causes skin irritation.

**pH:** 7.0 – 8.0 [When reconstituted]

**Serious Eye Damage/Irritation:** Causes serious eye damage.

**pH:** 7.0 – 8.0 [When reconstituted]

**Respiratory or Skin Sensitization:** Not classified.

**Germ Cell Mutagenicity:** Not classified.

**Carcinogenicity:** Not classified.

**Reproductive Toxicity:** Not classified.

**Specific Target Organ Toxicity (Single Exposure):** Not classified.

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified.

**Aspiration Hazard:** Not classified.

**Symptoms/Injuries After Inhalation:** Prolonged exposure may cause irritation.

**Symptoms/Injuries After Skin Contact:** Causes skin irritation.

**Symptoms/Injuries After Eye Contact:** Contact causes severe irritation with redness and swelling of the conjunctiva. Causes serious eye damage.

**Symptoms/Injuries After Ingestion:** Ingestion may cause adverse effects.

**Chronic Symptoms:** None expected under normal conditions of use.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Ecology - General** : Not classified.

| **Disodium carbonate (497-19-8)** | |
|---|---|
| **LC50 Fish 1** | 300 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static] Source: EPA) |
| **EC50 - Crustacea [1]** | 265 mg/l (Exposure time: 48 h - Species: Daphnia magna) |
| **LC50 Fish 2** | 310 – 1220 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static] Source: EPA) |

| **Sodium hydroxide (1310-73-2)** | |
|---|---|
| **LC50 Fish 1** | 45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static]) |
| **EC50 - Crustacea [1]** | 40 mg/l |

### 12.2. Persistence and Degradability

| **Ertapenem for Injection** | |
|---|---|
| **Persistence and Degradability** | Expected to be biodegradable. |

### 12.3. Bioaccumulative Potential

| **Ertapenem for Injection** | |
|---|---|
| **Bioaccumulative Potential** | Not expected to bioaccumulate. |

| **Disodium carbonate (497-19-8)** | |
|---|---|
| **BCF Fish 1** | (no bioaccumulation) |

### 12.4. Mobility in Soil

| **Ertapenem for Injection** | |
|---|---|
| **Ecology - Soil** | Adsorbs into the soil. Leaches if exposed to water. |

### 12.5. Other Adverse Effects

**Other Adverse Effects** : None known.

**Other Information** : Avoid release to the environment.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste Treatment Methods

**Waste Treatment Methods:** Incineration is the preferred method for disposal of waste product.

**Sewage Disposal Recommendations:** Do not dispose of waste into sewer. Do not empty into drains.

**Waste Disposal Recommendations:** Dispose of contents/container in accordance with local, regional, national, and international regulations.

**Additional Information:** Biologically contaminated materials should be incinerated.

**Ecology - Waste Materials:** Avoid unnecessary release into the environment.

## SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

### 14.1. In Accordance with DOT

Not regulated for transport

### 14.2. In Accordance with IMDG

Not regulated for transport

### 14.3. In Accordance with IATA

Not regulated for transport

## SECTION 15: REGULATORY INFORMATION

### 15.1. US Federal Regulations

| **Ertapenem for Injection** | |
|---|---|
| **SARA Section 311/312 Hazard Classes** | Health hazard - Serious eye damage or eye irritation<br>Health hazard - Skin corrosion or Irritation<br>Physical hazard - Combustible dust |

| **Disodium carbonate (497-19-8)** |
|---|
| Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active |

| **Sodium hydroxide (1310-73-2)** | |
|---|---|
| Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active | |
| **CERCLA RQ** | 1000 lb |

### 15.2. US State Regulations

| **Sodium hydroxide (1310-73-2)** |
|---|
| U.S. - New Jersey - Right to Know Hazardous Substance List |
| U.S. - Pennsylvania - RTK (Right to Know) List |
| U.S. - Massachusetts - Right To Know List |
| U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List |

## SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

**Date of Preparation or Latest Revision** : 05/14/2025

**Other Information** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

**GHS Full Text Phrases:**

| | |
|---|---|
| H290 | May be corrosive to metals |
| H302 | Harmful if swallowed |
| H312 | Harmful in contact with skin |
| H314 | Causes severe skin burns and eye damage |
| H315 | Causes skin irritation |
| H318 | Causes serious eye damage |
| H319 | Causes serious eye irritation |
| H402 | Harmful to aquatic life |

### Glossary of Data Source Abbreviations

ATSDR: Agency for Toxic Substances and Disease Registry (U.S. Department of Health and Human Services)
AU_WES: Australia WES
CHEMVIEW: ChemView (U.S. Environmental Protection Agency)
EC_RAR: European Commission Renewal Assessment Report
EC_SCOEL: European Commission Scientific Committee on Occupational Exposure Limits
ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals Reports
ECHA_API: European Chemicals Agency API
ECHA_RAC: ECHA Committee for Risk Assessment
EFSA: European Food Safety Authority
EPA: U.S. Environmental Protection Agency
EPA_AEGL: Acute Exposure Guideline Levels (U.S. Environmental Protection Agency)
EPA_FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act Reregistration Eligibility Decision (U.S. Environmental Protection Agency)
EPA_HPV: High Production Volume Chemicals (U.S. Environmental Protection Agency)
EPA_TRED: Risk Assessment for Tolerance Reassessment Eligibility Decision (U.S. Environmental Protection Agency)
EU_CLH: European Union Harmonised Classification and Labelling Proposal
EU_RAR: European Union Risk Assessment Report
FOOD_JOURN: Food Research Journal (1956)
IARC: The International Agency for Research on Cancer
IDLH: National Institute for Occupational Health and Safety Immediately Dangerous to Life or Health Value Profiles
IUCLID: International Uniform Chemical Information Database
JAPAN_GHS: Japan GHS Basis for Classification Data
JP_J-CHECK: Japan J-Check
KR_NIER: South Korea National Institute of Environmental Research Evaluations
NICNAS: Australia National Industrial Chemicals Notification and Assessment Scheme
NIOSH: National Institute for Occupational Health and Safety (U.S. Department of Health and Human Services)
NLM_CIP: National Library of Medicine ChemID plus database
NLM_HSDB: National Library of Medicine Hazardous Substance Data Bank
NLM_PUBMED: National Library of Medicine PubMed database
NTP: National Toxicology Program
NZ_CCID: New Zealand Chemical Classification and Information Database
OECD_EHSP: Environment, Health, and Safety Publication (Organisation for Economic Co-operation and Development)
OECD_SIDS: Screening Information Data Sets (Organisation for Economic Co-operation and Development)
WHO: World Health Organization

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*

SDS US (GHS HazCom)