SECTION-1: Identification of the substance / mixture and the company / undertaking

Catalogue Number	CS-T-54156
Product Name	Ertapenem
CAS No.	153832-46-3
Category	API
Synonyms	Not available
Brand	Clearsynth Labs Ltd.
Identified uses	Laboratory Chemicals
Uses advised against	Not available
Company	Clearsynth Labs Ltd. Mumbai, India
Emergency Phone #	+91-22-245045900
REACH No.	Not available

SECTION 2: Hazards identification

Disclaimer: This is sample MSDS. Please email **sales@clearsynth.com** for more details.

2.1 Classification of the substance or mixture-Regulation (EC) No 1272/2008:

Not available

2.2 Label Elements

Signal Word: Warning

Hazard Statement(s)

Code	Statement
H334	Not available
H400	Not available
H411	Toxic to aquatic life with long lasting effects.

Precautionary Statement(s)

Code	Statement
P233	Not available
P260	Not available
P271	Use only outdoors or in a well-ventilated area.
P273	Not available
P284	Not available
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P342+P316	Not available
P391	Not available
P403	Not available
P501	Dispose of contents/container in accordance with local/regional/national/international regulatio

SECTION 3: Composition / information on ingredients

3.1 Substance

Component : Ertapenem
CAS Number : 153832-46-3
Molecular Formula : C22H25N3O7S
Molecular Weight : 475.5
Parent Chemical : Ertapenem
Synonyms : Not available
Concentration : Not available

SECTION 4: First aid measures

Not available

SECTION 5: Firefighting measures

Not available

SECTION 6: Accidental release measures

Not available

SECTION-7: Handling and storage

Not available

SECTION 8: Exposure controls / personal protection

Not available

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Test	Result
Appearance	No data available
IR spectrum	No data available
pH	No data available
Solubility	No data available

Property	Value
a) Physical State	No data available
b) Color	No data available
c) Odor	No data available
d) pH	No data available
e) Vapour Pressure	No data available
f) Viscosity	No data available
g) Initial Boiling Point and boiling range	No data available
h) Melting Point / Freezing Point	No data available
i) Auto Ignition Temperature	No data available
j) Flash Point	No data available
k) Explosion Limit, Lower	No data available
l) Explosion Limit, Upper	No data available
m) Decomposition Temperature	No data available
n) Loss on Drying	No data available
o) Relative Density	No data available
p) Solubility (in DMSO)	No data available

Property	Value
q) Oxidizing Properties	No data available

SECTION 10: Stability and reactivity

Not available

SECTION 11: Toxicological information

11.1 Information on toxicological effects
- Acute toxicity: Mild, transient, asymptomatic elevations in serum aminotransferase levels occur in about 5% of patients receiving parenteral ertapenem for 5 to 14 days. These abnormalities are usually self-limited and asymptomatic. In the limited period that it has been available, no cases of hepatitis with jaundice have been reported. Nevertheless, several instances of cholestatic jaundice arising during or shortly after therapy have been reported with other carbapenems. The latency to onset has been within 1 to 3 weeks and the pattern of enzyme elevations is usually cholestatic. Immunoallergic features can occur but autoantibodies are rare. The course is usually self-limiting, but at least one case of vanishing bile duct syndrome related to a carbapenem has been reported. Ertapenem and other carbapenems have not been linked to cases of acute liver failure. Likelihood score: E* (unproven but suspected cause of clinically apparent liver injury). /SIGNS AND SYMPTOMS/ No specific information is available on the treatment of overdosage with ertapenem. Intentional overdosing of ertapenem is unlikely. Intravenous administration of ertapenem at a dose of 2 g over 30 min or 3 g over 1-2 hr in healthy adult volunteers resulted in an increased incidence of nausea. In clinical trials in adults, inadvertent administration of three 1 g doses of ertapenem in a 24 hour period resulted in diarrhea and transient dizziness in one patient. In pediatric clinical trials, a single intravenous dose of 40 mg/kg up to a maximum of 2 g did not result in toxicity.
- Skin corrosion/irritation: No data available.
- Serious eye damage/eye irritation: No data available.
- Respiratory or skin sensitization: No data available.
- Germ cell mutagenicity: /GENOTOXICITY/ Ertapenem was neither mutagenic nor genotoxic in the following in vitro assays: alkaline elution/rat hepatocyte assay, chromosomal aberration assay in Chinese hamster ovary cells, and TK6 human lymphoblastoid cell mutagenesis assay; and in the in vivo mouse micronucleus assay.
- Carcinogenicity: No data available.
- Reproductive toxicity: /LABORATORY ANIMALS: Developmental or Reproductive Toxicity/ In mice and rats given intravenous doses of up to 700 mg/kg/day (for mice, approximately 3 times the recommended human dose of 1 g based on body surface area and for rats, approximately 1.2 times the human exposure at the recommended dose of 1 g based on plasma AUCs), there was no evidence of developmental toxicity as assessed by external, visceral, and skeletal examination of the fetuses. However, in mice given 700 mg/kg/day, slight decreases in average fetal weights and an associated decrease in the average number of ossified sacrocaudal vertebrae were observed. /LABORATORY ANIMALS: Developmental or Reproductive Toxicity/ In mice and rats, iv doses of up to 700 mg/kg/day (for mice, approximately 3 times the recommended human dose of 1 g based on body surface area and for rats, approximately 1.2 times the human exposure at the recommended dose of 1 g based on plasma AUCs) resulted in no effects on mating performance, fecundity, fertility, or embryonic survival.
- STOT-single exposure: No data available.
- STOT-repeated exposure: /LABORATORY ANIMALS: Subchronic or Prechronic Exposure/ In repeat-dose studies in rats, treatment-related neutropenia occurred at every dose-level tested, including the lowest dose of 2 mg/kg (approximately 2% of the human dose on a body surface area basis). Studies in rabbits and Rhesus monkeys were

inconclusive with regard to the effect on neutrophil counts.
- Aspiration hazard: No data available.

Likely routes of exposure
- No data available.

Symptoms related to the physical, chemical and toxicological characteristics
- Mild, transient, asymptomatic elevations in serum aminotransferase levels occur in about 5% of patients receiving parenteral ertapenem for 5 to 14 days. These abnormalities are usually self-limited and asymptomatic. In the limited period that it has been available, no cases of hepatitis with jaundice have been reported. Nevertheless, several instances of cholestatic jaundice arising during or shortly after therapy have been reported with other carbapenems. The latency to onset has been within 1 to 3 weeks and the pattern of enzyme elevations is usually cholestatic. Immunoallergic features can occur but autoantibodies are rare. The course is usually self-limiting, but at least one case of vanishing bile duct syndrome related to a carbapenem has been reported. Ertapenem and other carbapenems have not been linked to cases of acute liver failure. Likelihood score: E* (unproven but suspected cause of clinically apparent liver injury).

SECTION 12: Ecological information

Not available

SECTION 13: Disposal considerations

Not available

SECTION 14: Transport information

Not available

SECTION 15: Regulatory information

Not available

SECTION 16: Other information

Not available

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