

## Ertapenem Formulation

Version 7.1      Revision Date: 26.09.2023      SDS Number: 20987-00021      Date of last issue: 20.03.2023  
Date of first issue: 03.11.2014

---

### Section 1: Identification

Product name : Ertapenem Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908  
Upper Hutt - New Zealand

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

---

### Section 2: Hazard identification

#### GHS Classification

Respiratory sensitisation : Category 1

Hazardous to the aquatic environment - acute hazard : Category 1

Hazardous to the aquatic environment - chronic hazard : Category 2

#### GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H400 Very toxic to aquatic life.  
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P261 Avoid breathing dust.

## Ertapenem Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
7.1	26.09.2023	20987-00021	Date of first issue: 03.11.2014

P273 Avoid release to the environment.  
P284 Wear respiratory protection.

**Response:**

P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.  
P391 Collect spillage.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards which do not result in classification**

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

**Section 3: Composition/information on ingredients**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Ertapenem	153773-82-1	>= 70 -< 90

**Section 4: First-aid measures**

General advice : 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.  
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.

If inhaled : If inhaled, remove to fresh air.  
If not breathing, give artificial respiration.  
If breathing is difficult, give oxygen.  
Get medical attention.

In case of skin contact : Wash with water and soap.  
Get medical attention if symptoms occur.

In case of eye contact : If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and : May cause allergy or asthma symptoms or breathing difficulties if inhaled.

## Ertapenem Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
7.1	26.09.2023	20987-00021	Date of first issue: 03.11.2014

---

delayed		Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome). Contact with dust can cause mechanical irritation or drying of the skin.
Protection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

---

**Section 5: Fire-fighting measures**

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Metal oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Hazchem Code	:	2Z

---

**Section 6: Accidental release measures**

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Surround spill with absorbents and place a damp covering over the area to minimise entry of the material into the air. Add excess liquid to allow the material to enter into solution. Soak up with inert absorbent material.

## Ertapenem Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
7.1	26.09.2023	20987-00021	Date of first issue: 03.11.2014

---

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.  
 Clean up remaining materials from spill with suitable absorbent.  
 Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
 Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

---

**Section 7: Handling and storage**

- |                             |   |  |
|-----------------------------|---|--|
| Technical measures          | : | Static electricity may accumulate and ignite suspended dust causing an explosion.<br>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.   |
| Local/Total ventilation     | : | Use only with adequate ventilation.  |
| Advice on safe handling     | : | Avoid breathing dust.<br>Do not swallow.<br>Avoid contact with eyes.<br>Avoid prolonged or repeated contact with skin.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures            | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.   |
| Conditions for safe storage | : | Keep in properly labelled containers.<br>Keep tightly closed.<br>Store in accordance with the particular national regulations.   |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents  |

## Ertapenem Formulation

Version 7.1      Revision Date: 26.09.2023      SDS Number: 20987-00021      Date of last issue: 20.03.2023  
 Date of first issue: 03.11.2014

## Section 8: Exposure controls/personal protection

## Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ertapenem	153773-82-1	TWA	0.15 mg/m <sup>3</sup> (OEB 2)	Internal
Further information: RSEN				

**Engineering measures** : Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

**Personal protective equipment**

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:  
Safety goggles

Skin and body protection : Skin should be washed after contact.

## Section 9: Physical and chemical properties

Appearance : powder

Colour : white

Odour : No data available

Odour Threshold : No data available

pH : No data available

**Ertapenem Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
7.1	26.09.2023	20987-00021	Date of first issue: 03.11.2014

---

Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

**Ertapenem Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
7.1	26.09.2023	20987-00021	Date of first issue: 03.11.2014

---

**Section 10: Stability and reactivity**

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

---

**Section 11: Toxicological information**

Exposure routes	:	Inhalation Skin contact Ingestion Eye contact
-----------------	---	--

**Acute toxicity**

Not classified based on available information.

**Components:****Ertapenem:**

Acute oral toxicity	:	LD50 (Mouse): > 500 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Mouse): > 700 mg/kg Application Route: Intravenous  LD50 (Rat): > 700 mg/kg Application Route: Intravenous

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Ertapenem:**

Species	:	Rabbit
Result	:	No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Ertapenem:**

Species	:	Rabbit
Result	:	Mild eye irritation

**Ertapenem Formulation**

Version 7.1      Revision Date: 26.09.2023      SDS Number: 20987-00021      Date of last issue: 20.03.2023  
Date of first issue: 03.11.2014

---

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Components:****Ertapenem:**

Exposure routes                               : inhalation (dust/mist/fume)  
Assessment                                       : Probability of respiratory sensitisation in humans based on animal testing  
Result   : positive

**Chronic toxicity****Germ cell mutagenicity**

Not classified based on available information.

**Components:****Ertapenem:**

Genotoxicity in vitro                               : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
  
Test Type: Alkaline elution assay  
Test system: rat hepatocytes  
Result: negative  
  
Test Type: Chromosomal aberration  
Test system: Chinese hamster ovary cells  
Result: negative  
  
Test Type: In vitro mammalian cell gene mutation test  
Test system: human lymphoblastoid cells  
Result: negative  
  
Genotoxicity in vivo                               : Test Type: Micronucleus test  
Species: Mouse  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Reproductive toxicity**

Not classified based on available information.

**Components:****Ertapenem:**



## Ertapenem Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
7.1	26.09.2023	20987-00021	Date of first issue: 03.11.2014

---

Effects on fertility : Test Type: Fertility/early embryonic development  
 Species: Rat  
 Application Route: Intravenous  
 Fertility: NOAEL: 700 mg/kg body weight  
 Result: No effects on fertility and early embryonic development were detected.

Test Type: Fertility  
 Species: Mouse  
 Fertility: NOAEL: 700  
 Result: No effects on fertility

Effects on foetal development : Test Type: Development  
 Species: Mouse  
 Application Route: Intravenous injection  
 Developmental Toxicity: NOAEL: 700 mg/kg body weight  
 Result: No effects on early embryonic development

Test Type: Development  
 Species: Mouse  
 Application Route: Intravenous injection  
 Developmental Toxicity: NOAEL: 350 mg/kg body weight  
 Symptoms: Reduced body weight  
 Remarks: The mechanism or mode of action may not be relevant in humans.

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Not classified based on available information.

**Repeated dose toxicity****Components:****Ertapenem:**

Species : Rat  
 LOAEL : 2 mg/kg  
 Application Route : Intravenous  
 Exposure time : 2 Weeks  
 Target Organs : Blood  
 Remarks : The mechanism or mode of action may not be relevant in humans.

Species : Rat  
 LOAEL : 60 mg/kg  
 Application Route : Intravenous  
 Exposure time : 6 Months  
 Target Organs : Blood  
 Remarks : The mechanism or mode of action may not be relevant in humans.

## Ertapenem Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
7.1	26.09.2023	20987-00021	Date of first issue: 03.11.2014

---

Species	:	Monkey
NOAEL	:	360 mg/kg
LOAEL	:	500 mg/kg
Application Route	:	Intravenous
Exposure time	:	27 Weeks
Target Organs	:	Liver, Kidney
Remarks	:	The mechanism or mode of action may not be relevant in humans.

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Ertapenem:**

Inhalation	:	Remarks: May cause sensitisation by inhalation.
Ingestion	:	Symptoms: Diarrhoea, Nausea, Headache, vaginitis

---

**Section 12: Ecological information****Ecotoxicity****Components:****Ertapenem:**

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l Exposure time: 96 h
------------------	---	--

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 500 mg/l Exposure time: 48 h
---	---	--

Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 51 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
----------------------------------	---	---

NOEC (Pseudokirchneriella subcapitata (green algae)): 51 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae): 0.23 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 0.13 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-	:	1
------------------------------	---	---

**Ertapenem Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
7.1	26.09.2023	20987-00021	Date of first issue: 03.11.2014

---

icity)  
Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 2.5 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 82 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

Toxicity to microorganisms : EC10: 3.9 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition

**Persistence and degradability****Components:****Ertapenem:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 4.7 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

Stability in water : Degradation half life (DT50): 15.3 d

**Bioaccumulative potential****Components:****Ertapenem:**

Partition coefficient: n-octanol/water : log Pow: -2.22

**Mobility in soil**

No data available

**Other adverse effects**

No data available

---

**Section 13: Disposal considerations****Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

---

**Section 14: Transport information****International Regulations**

**Ertapenem Formulation**

Version 7.1      Revision Date: 26.09.2023      SDS Number: 20987-00021      Date of last issue: 20.03.2023  
Date of first issue: 03.11.2014

---

**UNRTDG**

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.  
(Ertapenem)  
Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : yes

**IATA-DGR**

UN/ID No. : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Ertapenem)  
Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 956  
Packing instruction (passenger aircraft) : 956  
Environmentally hazardous : yes

**IMDG-Code**

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.  
(Ertapenem)  
Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**National Regulations****NZS 5433**

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.  
(Ertapenem)  
Class : 9  
Packing group : III  
Labels : 9  
Hazchem Code : 2Z  
Marine pollutant : no

**Special precautions for user**

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data

## Ertapenem Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
7.1	26.09.2023	20987-00021	Date of first issue: 03.11.2014

---

Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

---

### Section 15: Regulatory information

#### Safety, health and environmental regulations/legislation specific for the substance or mixture

##### HSNO Approval Number

HSR100425 Pharmaceutical Active Ingredients Group Standard

##### HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

#### The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

---

### Section 16: Other information

Revision Date : 26.09.2023

#### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

#### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Or-

**Ertapenem Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
7.1	26.09.2023	20987-00021	Date of first issue: 03.11.2014

---

ganisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

NZ / EN