1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Ertapenem Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Briahnager - Off Pune Nagar Road Wagholi - Pune - India 412 207
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989
Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Respiratory sensitisation: Category 1
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic 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.
- 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 + P316 If experiencing respiratory symptoms: Get emergency medical help immediately.
- 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.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ertapenem</td>
<td></td>
<td>153773-82-1</td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
</tbody>
</table>

### 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.

**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.
SAFETY DATA SHEET

Ertapenem Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.4</td>
<td>16.10.2020</td>
<td>20977-00015</td>
<td>23.03.2020</td>
<td>03.11.2014</td>
</tr>
</tbody>
</table>

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: 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.

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: 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.
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.

7. HANDLING AND STORAGE

**Technical measures**: Static electricity may accumulate and ignite suspended dust causing an explosion. 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.
- Do not swallow.
- Avoid contact with eyes.
- Avoid prolonged or repeated contact with skin.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers.
- 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**:
- Keep in properly labelled containers.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

**Materials to avoid**:
- Do not store with the following product types:
  - Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Components with workplace control parameters**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ertapenem</td>
<td>153773-82-1</td>
<td>TWA</td>
<td>0.15 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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.
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**
- **Remarks**: Wear the following personal protective equipment:
  - Safety goggles

**Skin and body protection**
- **Remarks**: Skin should be washed after contact.

**Hygiene measures**
- **Remarks**: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td>powder</td>
</tr>
<tr>
<td><strong>Colour</strong></td>
<td>white</td>
</tr>
<tr>
<td><strong>Odour</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Odour Threshold</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Melting point/freezing point</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Initial boiling point and boiling range</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flammability (solid, gas)</strong></td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td><strong>Flammability (liquids)</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Upper explosion limit / Upper</strong></td>
<td>No data available</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
Ertapenem Formulation

flammability limit
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

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.

11. TOXICOLOGICAL INFORMATION
Information on likely routes of exposure : 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

**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

**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:

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 rele-
### Repeated dose toxicity

**Components:**

<table>
<thead>
<tr>
<th>Ertapenem:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Species</strong></td>
<td>Rat</td>
</tr>
<tr>
<td><strong>LOAEL</strong></td>
<td>2 mg/kg</td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>Intravenous</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>2 Weeks</td>
</tr>
<tr>
<td><strong>Target Organs</strong></td>
<td>Blood</td>
</tr>
<tr>
<td><strong>Remarks</strong></td>
<td>The mechanism or mode of action may not be relevant in humans.</td>
</tr>
</tbody>
</table>

| 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. |

| 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:**

<table>
<thead>
<tr>
<th>Ertapenem:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inhalation</strong></td>
</tr>
<tr>
<td><strong>Ingestion</strong></td>
</tr>
</tbody>
</table>
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 toxicity):
- 1

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

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

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

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

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : 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.

14. TRANSPORT INFORMATION

International Regulations

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

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 IMO instruments
Not applicable for product as supplied.

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

15. REGULATORY INFORMATION

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

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information
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
SAFETY DATA SHEET

Ertapenem Formulation

Version 4.4  Revision Date: 16.10.2020  SDS Number: 20977-00015  Date of last issue: 23.03.2020  Date of first issue: 03.11.2014

- 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 Organization 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; 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.

IN / EN