

**Daptomycin Injection Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 06.04.2024  |
| 3.3     | 14.04.2025     | 650803-00019 | Date of first issue: 02.05.2016 |

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**Section 1: Identification**

**Product identifier** : Daptomycin Injection Formulation

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

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

**Manufacturer or supplier's details**

Company : MSD  
Address : 50 Tuas West Drive  
Singapore - Singapore 638408  
Telephone : +1-908-740-4000  
Emergency telephone number : 65 6697 2111 (24/7/365)  
E-mail address : EHSDATASTEWARD@msd.com

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**Section 2: Hazard identification**

**Classification of the substance or mixture**

Specific target organ toxicity - repeated exposure (Dermal) : Category 2 (muscle, Kidney, Nervous system)

**GHS Label elements, including precautionary statements**

Hazard pictograms :



Signal word : Warning

Hazard statements : H373 May cause damage to organs (muscle, Kidney, Nervous system) through prolonged or repeated exposure in contact with skin.

Precautionary statements :  
**Prevention:**  
P260 Do not breathe dust.  
**Response:**  
P314 Get medical advice/ attention if you feel unwell.  
**Disposal:**  
P501 Dispose of contents/ container to an approved waste

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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) |
|---------------|-------------|-----------------------|
| Daptomycin    | 103060-53-3 | >= 90 -<= 100         |

**Section 4: First-aid measures****Description of necessary 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.  
Get medical attention if symptoms occur.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
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 delayed**

Risks : Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.  
May cause damage to organs through prolonged or repeated exposure in contact with skin.

Protection of first-aiders : 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).

**Indication of any immediate medical attention and special treatment needed**

Treatment : Treat symptomatically and supportively.

**Section 5: Fire-fighting measures****Extinguishing media**

Suitable extinguishing media : Water spray

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Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

**Special hazards arising from the substance or mixture**

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

**Special protective actions for fire-fighters**

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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.

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**Section 6: Accidental release measures****Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**Environmental precautions**

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**

Methods for 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 dis-

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posal 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.

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**Section 7: Handling and storage****Precautions for safe handling**

- |                         |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 | : | Do not get on skin or clothing.<br>Do not breathe dust.<br>Do not swallow.<br>Avoid contact with eyes.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<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.<br>The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.                    |

**Conditions for safe storage, including any incompatibilities**

- |                             |   |                                                                                                        |
|-----------------------------|---|--------------------------------------------------------------------------------------------------------|
| Conditions for safe storage | : | Keep in properly labelled containers.<br>Store in accordance with the particular national regulations. |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents                              |

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**Section 8: Exposure controls/personal protection****Control parameters****Occupational Exposure Limits**

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| Components | CAS-No.     | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | Basis    |
|------------|-------------|----------------------------------|------------------------------------------------|----------|
| Daptomycin | 103060-53-3 | TWA                              | 800 µg/m <sup>3</sup> (OEB 2)                  | Internal |

**Appropriate engineering control measures** : Use feasible engineering controls to minimize exposure to compound.  
 All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

**Individual protection measures, such as personal protective equipment (PPE)**

Eye/face protection : Wear safety glasses with side shields or goggles.  
 If 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 : Work uniform or laboratory coat.

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 : Chemical-resistant gloves

Material

## Section 9: Physical and chemical properties

Appearance : lyophilised cake

Colour : light brown

Odour : No data available

Odour Threshold : No data available

pH : 4.5 - 5

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : Not applicable

Evaporation rate : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

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|                                                  |   |                                                          |
|--------------------------------------------------|---|----------------------------------------------------------|
| 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           | : | Not applicable                                           |
| Auto-ignition temperature                        | : | No data available                                        |
| Decomposition temperature                        | : | No data available                                        |
| Viscosity                                        | : |                                                          |
| Viscosity, kinematic                             | : | No data available                                        |
| Explosive properties                             | : | Not explosive                                            |
| Oxidizing properties                             | : | The substance or mixture is not classified as oxidizing. |
| Particle characteristics                         | : |                                                          |
| Particle size                                    | : | No data available                                        |

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**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.<br>Can react with strong oxidizing agents. |
| Conditions to avoid                | : | Heat, flames and sparks.<br>Avoid dust formation.                                                                          |
| Incompatible materials             | : | Oxidizing agents                                                                                                           |
| Hazardous decomposition products   | : | No hazardous decomposition products are known.                                                                             |

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**Section 11: Toxicological information**

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Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Daptomycin:**

|         |                        |
|---------|------------------------|
| Species | : Rabbit               |
| Result  | : Mild skin irritation |

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Daptomycin:**

|         |                       |
|---------|-----------------------|
| Species | : Rabbit              |
| Result  | : Mild eye irritation |

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

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Daptomycin:**

|                       |                                                                          |
|-----------------------|--------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |
|-----------------------|--------------------------------------------------------------------------|

|  |                                                                    |
|--|--------------------------------------------------------------------|
|  | Test Type: Chromosome aberration test in vitro<br>Result: negative |
|--|--------------------------------------------------------------------|

|  |                                                                                                                |
|--|----------------------------------------------------------------------------------------------------------------|
|  | Test Type: In vitro mammalian cell gene mutation test<br>Test system: mouse lymphoma cells<br>Result: negative |
|--|----------------------------------------------------------------------------------------------------------------|

|  |                                                                                                               |
|--|---------------------------------------------------------------------------------------------------------------|
|  | Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)<br>Result: negative |
|--|---------------------------------------------------------------------------------------------------------------|

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Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo  
Species: Hamster  
Application Route: Intraperitoneal injection  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Reproductive toxicity**

Not classified based on available information.

**Components:****Daptomycin:**

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Intravenous injection  
Fertility: NOAEL: 150 mg/kg body weight  
Result: No effects on fertility

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Intravenous injection  
Developmental Toxicity: NOAEL: 75 mg/kg body weight  
Result: No significant adverse effects were reported

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Intravenous injection  
Developmental Toxicity: NOAEL: 75 mg/kg body weight  
Result: No significant adverse effects were reported

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

May cause damage to organs (muscle, Kidney, Nervous system) through prolonged or repeated exposure in contact with skin.

**Components:****Daptomycin:**

Target Organs : muscle, Kidney, Nervous system



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Assessment : May cause damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Daptomycin:**

|                   |                   |
|-------------------|-------------------|
| Species           | : Dog             |
| NOAEL             | : 20 mg/kg        |
| LOAEL             | : 40 mg/kg        |
| Application Route | : Intravenous     |
| Exposure time     | : 3 Months        |
| Target Organs     | : Skeletal muscle |

|                   |                                                |
|-------------------|------------------------------------------------|
| Species           | : Monkey                                       |
| NOAEL             | : 10 mg/kg                                     |
| Application Route | : Intravenous                                  |
| Exposure time     | : 1 Months                                     |
| Remarks           | : No significant adverse effects were reported |

|                   |                                   |
|-------------------|-----------------------------------|
| Species           | : Dog                             |
| Application Route | : Intravenous                     |
| Exposure time     | : 28 Days                         |
| Target Organs     | : Skeletal muscle, Nervous system |
| Symptoms          | : muscle twitching                |

|                   |                                   |
|-------------------|-----------------------------------|
| Species           | : Juvenile dog                    |
| LOAEL             | : 50 mg/kg                        |
| Application Route | : Intravenous                     |
| Exposure time     | : 28 Days                         |
| Target Organs     | : Skeletal muscle, Nervous system |

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Daptomycin:**

|                     |                                        |
|---------------------|----------------------------------------|
| General Information | : Symptoms: Rash, Diarrhoea, vaginitis |
|---------------------|----------------------------------------|

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**Section 12: Ecological information****Toxicity**

No data available

**Persistence and degradability**

No data available

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**Bioaccumulative potential**

No data available

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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

|                        |   |                                                                                                                                                             |
|------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Waste from residues    | : | Do not dispose of waste into sewer.<br>Dispose of in accordance with local regulations.                                                                     |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product. |

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

|                            |   |                |
|----------------------------|---|----------------|
| UN number                  | : | Not applicable |
| UN proper shipping name    | : | Not applicable |
| Transport hazard class(es) | : | Not applicable |
| Subsidiary risk            | : | Not applicable |
| Packing group              | : | Not applicable |
| Labels                     | : | Not applicable |
| Environmentally hazardous  | : | no             |

**IATA-DGR**

|                                          |   |                |
|------------------------------------------|---|----------------|
| UN/ID No.                                | : | Not applicable |
| UN proper shipping name                  | : | Not applicable |
| Transport hazard class(es)               | : | Not applicable |
| Subsidiary risk                          | : | Not applicable |
| Packing group                            | : | Not applicable |
| Labels                                   | : | Not applicable |
| Packing instruction (cargo aircraft)     | : | Not applicable |
| Packing instruction (passenger aircraft) | : | Not applicable |

**IMDG-Code**

|                            |   |                |
|----------------------------|---|----------------|
| UN number                  | : | Not applicable |
| UN proper shipping name    | : | Not applicable |
| Transport hazard class(es) | : | Not applicable |
| Subsidiary risk            | : | Not applicable |
| Packing group              | : | Not applicable |
| Labels                     | : | Not applicable |
| EmS Code                   | : | Not applicable |
| Marine pollutant           | : | Not applicable |

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**Transport in bulk according to IMO instruments**

Not applicable for product as supplied.

**Special precautions for user**

Not applicable

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**Section 15: Regulatory information****Safety, health and environmental regulations specific for the product in question**

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subject to the requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable

Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable  
Regulations

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

AICS : not determined

DSL : not determined

IECSC : not determined

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**Section 16: Other information**

Revision Date : 14.04.2025

**Further information**

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD  
compile the Safety Data eChem Portal search results and European Chemicals Agen-  
Sheet cy, <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-

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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.

SG / EN