

# SAFETY DATA SHEET



## Daptomycin Injection Formulation - 2nd Generation

Version 4.2      Revision Date: 14.04.2025      SDS Number: 679939-00019      Date of last issue: 30.09.2023  
Date of first issue: 19.05.2016

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### Section 1: Identification

Product name : Daptomycin Injection Formulation - 2nd Generation

#### Manufacturer or supplier's details

Company : MSD

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

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON)    0800 243 622 (0800  
CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

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### Section 2: Hazard identification

#### GHS Classification

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

#### GHS label elements

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 : **Response:**

P314 Get medical advice/ attention if you feel unwell.

**Disposal:**

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

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### 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.

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### Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Sucrose	57-50-1	>= 50 -< 70
Daptomycin	103060-53-3	>= 30 -< 50

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### 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.

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 : 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).

Notes to physician : Treat symptomatically and supportively.

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### 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.

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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
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.

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**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	: 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.

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**Section 7: Handling and storage**

Technical measures	: Static electricity may accumulate and ignite suspended dust
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Local/Total ventilation	causing an explosion.
Advice on safe handling	Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
	: Use only with adequate ventilation.
	: Do not get on skin or clothing.
	Do not breathe dust.
	Do not swallow.
	Avoid contact with eyes.
	Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
	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.
Hygiene measures	: 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.
	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	: Keep in properly labelled containers.
Materials to avoid	: Store in accordance with the particular national regulations.
	: Do not store with the following product types:
	Strong oxidizing agents

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**Section 8: Exposure controls/personal protection****Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Sucrose	57-50-1	WES-TWA	10 mg/m3	NZ OEL
		TWA	10 mg/m3	ACGIH
Daptomycin	103060-53-3	TWA	800 µg/m3 (OEB 2)	Internal

Engineering 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.
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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
Eye 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 and body protection	: Work uniform or laboratory coat.

**Section 9: Physical and chemical properties**

Appearance	: lyophilised cake
Colour	: light brown
Odour	: No data available
Odour Threshold	: No data available
pH	: 6.5 - 7.3 (as aqueous solution)
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.
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

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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. 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.

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### Section 11: Toxicological information

Exposure routes	:	Inhalation Skin contact Ingestion Eye contact
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#### Acute toxicity

Not classified based on available information.

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Acute oral toxicity : LD50 (Rat): 29,700 mg/kg

**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.

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

Not classified based on available information.

**Components:****Sucrose:**Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative**Daptomycin:**Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negativeTest Type: Chromosome aberration test in vitro  
Result: negative

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Test Type: In vitro mammalian cell gene mutation test  
Test system: mouse lymphoma cells  
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: negative

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.

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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  
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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No data available

**Persistence and degradability**

No data available

**Bioaccumulative potential****Components:****Sucrose:**

Partition coefficient: n-octanol/water : Pow: &lt; 1

**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****UNRTDG**

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Environmentally hazardous	:	no

**IATA-DGR**

UN/ID No.	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable

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Packing instruction (cargo aircraft) : Not applicable

Packing instruction (passenger aircraft) : Not applicable

### IMDG-Code

UN number : Not applicable

Proper shipping name : Not applicable

Class : Not applicable

Subsidiary risk : Not applicable

Packing group : Not applicable

Labels : Not applicable

EmS Code : Not applicable

Marine pollutant : Not applicable

### 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 : Not applicable

Proper shipping name : Not applicable

Class : Not applicable

Subsidiary risk : Not applicable

Packing group : Not applicable

Labels : Not applicable

Hazchem Code : Not applicable

### Special precautions for user

Not applicable

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## 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

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

#### 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:**

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AICS : not determined  
DSL : not determined  
IECSC : not determined

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**Section 16: Other information**

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**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**

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
NZ OEL	: New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
ACGIH / TWA	: 8-hour, time-weighted average
NZ OEL / WES-TWA	: Workplace Exposure Standard - Time Weighted average

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 Organisation 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 - Trans-

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portion 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