

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Dapto-AUS/DP-001

Effective Date: 03rd April 2020

Daptomycin, Powder for Injection, 350 mg/vial and 500 mg/vial

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Daptomycin, Powder for Injection, 350 mg/vial and 500 mg/vial

Manufacturer or supplier's details

Manufacturer:

Intas Pharmaceuticals Ltd.
Plot No. 457, 458
Sarkhej-Bavla Highway,
Matoda, Tal. Sanand,
Dist. Ahmedabad- 382210, Gujarat,
India

Sponsor:

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street,
Melbourne, VIC, 3000,
Australia

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2 – COMPOSITION, INFORMATION ON INGREDIENTS

Chemical name	CAS-No.	Concentration (% w/w)
Daptomycin	103060-53-3	>= 60 - <= 100

Inactive: Sodium Hydroxide and Water for injections

SECTION 3 - HAZARDS IDENTIFICATION

GHS Classification:

Specific target organ toxicity - repeated exposure (Dermal)

Category 2 (muscle, Kidney, Nervous system)

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

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Precautionary statements:

Prevention:

P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.

Response:

P314 Get medical advice/ attention if you feel unwell.

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 4 - EMERGENCY & 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:

May cause damage to organs through prolonged or repeated exposure in contact with skin.

Contact with dust can cause mechanical irritation or drying of the skin.

Dust contact with the eyes can lead to mechanical irritation.

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 ₂) 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
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.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment.

Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions:

Discharge into the environment must be avoided.

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 re-released into the atmosphere in sufficient concentration.

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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. 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. 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. Store in accordance with the particular national regulations.
Materials to avoid:	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 parameters / Permissible concentration	Basis
Daptomycin	103060-53-3	TWA	0.4 mg/m ³ (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.

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: 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: 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.
Flammability (liquids): No data available

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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:	
Viscosity	No data available
Viscosity, kinematic:	
Explosive properties:	Not explosive
Oxidizing properties:	The substance or mixture is not classified as oxidizing.
Particle size:	No data available

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 - TOXICOLOGY INFORMATION

Exposure routes:	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

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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:

Daptomycin:

Genotoxicity in vitro:

Test Type	Result
Bacterial reverse mutation assay (AMES)	negative
Chromosome aberration test in vitro	negative
In vitro mammalian cell gene mutation test Test system: mouse lymphoma cells	negative
DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)	Negative

Genotoxicity in vivo:

Test Type	Species	Application Route	Result
Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)	Mouse	Intraperitoneal injection	negative
Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo	Hamster	Intraperitoneal injection	negative

Carcinogenicity: Not classified based on available information.

Reproductive toxicity: Not classified based on available information.

Components:

Daptomycin:

Effects on fertility:

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

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Effects on foetal development:

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

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

Repeated dose toxicity:

Components:

Daptomycin:

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

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

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

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

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

Aspiration toxicity: Not classified based on available information.

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Experience with human exposure

Components:

Daptomycin:

General Information: Symptoms: Rash, Diarrhoea, vaginitis

SECTION 12 - ENVIRONMENTAL IMPACT INFORMATION

Ecotoxicity: No data available

Persistence and degradability: No data available

Bioaccumulative potential: No data available

Mobility in soil: No data available

Other adverse effects: No data available

SECTION 13 - DISPOSAL INFORMATION

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.

SECTION 14 - TRANSPORTATION INFORMATION

International Regulations

UNRTDG: Not regulated as a dangerous good

IATA-DGR: Not regulated as a dangerous good

IMDG-Code: Not regulated as a dangerous good

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

National Regulations

ADG: Not regulated as a dangerous good

SECTION 15 - REGULATORY INFORMATION

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

Prohibition/Licensing Requirements: There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

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

AICS: not determined
DSL: not determined
IECS: not determined

SECTION 16 - OTHER DATA

Sources of key data used to compile the Safety Data Sheet: Information from published literature.

Full text of other abbreviations:	
AICS:	Australian Inventory of Chemical Substances
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 Sys-tem;
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 con-centration
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 Con-centration 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

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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

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