

Version 3.2	Revision Date: 06.04.2024		S Number: 0803-00018	Date of last issue: 30.09.2023 Date of first issue: 02.05.2016
Section 1	l: Identification			
Proc	luct identifier	:	Daptomycin Inje	ction Formulation
Reco	ommended use of the cl	hem	ical and restricti	ons on use
	ommended use rictions on use	:	Pharmaceutical Not applicable	
Man	ufacturer or supplier's o	deta	ils	
Com	pany	:	MSD	
Addr	ess	:	50 Tuas West D Singapore - Sin	-
Tele	phone	:	+1-908-740-400	0
Eme	rgency telephone numbe	r :	65 6697 2111 (2	4/7/365)
E-ma	ail address	:	EHSDATASTEV	VARD@msd.com
Section 2	2: Hazard identification			
Clas	sification of the substa	nce	or mixture	
	cific target organ toxicity - ated exposure (Dermal)	:	Category 2 (mus	cle, Kidney, Nervous system)
GHS	Label elements, includ	ing	precautionary st	atements
Haza	ard pictograms	:		
Sign	al word	:	Warning	
Haza	ard statements	:		e damage to organs (muscle, Kidney, Nervous prolonged or repeated exposure in contact

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 fi	rst-ai	d measures
General advice		In the case of accident or if you feel unwell, seek medical ad- vice 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 e	effects, both acute and delayed
Risks		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).
Indication of any immediat	e mec	dical 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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itable extinguishing	:		
	n th	e substance or	mixture
ific hazards during fire-	:	Avoid generatin concentrations, potential dust ex	g dust; fine dust dispersed in air in sufficient and in the presence of an ignition source is a xplosion hazard. nbustion products may be a hazard to health.
rdous combustion prod-	:	Carbon oxides	
•		In the event of f Use personal pr Use extinguishin cumstances and Use water spray	ire, wear self-contained breathing apparatus. rotective equipment. Ing measures that are appropriate to local cir- d the surrounding environment. y to cool unopened containers. laged containers from fire area if it is safe to do
		uipment and en Use personal pr Follow safe han	otective equipment. dling advice (see section 7) and personal pro-
ental precautions onmental precautions	:	Avoid release to Prevent further Retain and disp Local authorities	nt recommendations (see section 8). o the environment. leakage or spillage if safe to do so. ose of contaminated wash water. s should be advised if significant spillages lined.
and materials for conta ods for cleaning up	iinn :	Sweep up or va tainer for dispose Avoid dispersal with compresse Dust deposits si es, as these ma leased into the a Local or nationa posal of this ma employed in the mine which regu	cuum up spillage and collect in suitable con- al. of dust in the air (i.e., clearing dust surfaces
	06.04.2024 itable extinguishing a ial hazards arising from ific hazards during fire- ig rdous combustion prod- ial protective actions for ial protective equipment efighters ific extinguishing meth- : Accidental release methonal precautions ental precautions ental precautions and materials for conta	06.04.2024 65 itable extinguishing : ial hazards arising from the : ific hazards during fire- : ig : rdous combustion prod- : ial protective actions for file ial protective equipment : ial protective equipment : efighters : ific extinguishing meth- : : Accidental release measure precautions, protective equipment precautions, protective equipment : ental precautions : ental precautions : and materials for containm :	06.04.2024 650803-00018 Alcohol-resistar Carbon dioxide Dry chemical itable extinguishing None known. ial hazards arising from the substance or fic hazards during fire- ng Avoid generatin concentrations, potential dust ex Exposure to cor ial protective actions for fire-fighters In the event of f ial protective equipment In the event of f efighters Use personal price fic extinguishing meth- Use extinguishind cumstances and Use water spray Remove undam so. Evacuate area. Evacuate area. Exocidental release measures Follow safe han tective equipment and precautions precautions, protective equipment and en onal precautions Youd release to Prevent further Retain and disp Local authorities cannot be conta and materials for containment and cleanin ods for cleaning up Sweep up or va tainer for dispos Avoid dispersal with compresse Dust deposits si es, as these ma leased into the a Local or nationa posal of this ma employed in the mine which reguine



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		certain local c	or national requirements.
Section 7	: Handling and storage	9	
Preca	autions for safe handli	ng	
Techi	nical measures	causing an ex Provide adeq	ity may accumulate and ignite suspended dust plosion. uate precautions, such as electrical grounding or inert atmospheres.
	/Total ventilation e on safe handling	 Use only with Do not get on Do not breath Do not swallo Avoid contact Handle in acc practice, base sessment Minimize dust Keep contain Keep away free Take precauti 	adequate ventilation. skin or clothing. e dust. w.
Hygie	ene measures	: If exposure to flushing syste place. When using c Wash contam The effective engineering c appropriate d industrial hyg	chemical is likely during typical use, provide eye ms and safety showers close to the working lo not eat, drink or smoke. inated clothing before re-use. operation of a facility should include review of ontrols, proper personal protective equipment, egowning and decontamination procedures, iene monitoring, medical surveillance and the strative controls.
Cond	litions for safe storage	e, including any in	compatibilities
	itions for safe storage rials to avoid	Store in acco	erly labelled containers. rdance with the particular national regulations. with the following product types: ng agents

Section 8: Exposure controls/personal protection

Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
		exposure)	concentration	



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D	Daptomycin			103060-53-3	TWA	800 µg/m3 (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. 						
In	ndivid	lual protection meas	ure	s, such as pers	onal protective	e equipment (PPE)				
E	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 Respiratory protection			Work uniform or laboratory coat. If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.						
Н	Filter type Hand protection Material			Particulates type Chemical-resistant gloves						
Sectio	on 9:	Physical and chemic	al p	roperties						
A	Appearance			lyophilised cake						
С	Colour		:	light brown						
0	Ddour		:	No data avai	lable					
0	Odour Threshold			No data avai	No data available					

pH : 4.5 - 5 Melting point/freezing point : No data available

- Initial boiling point and boiling : No data available range
- Flash point:Not applicableEvaporation rate:No data availableFlammability (solid, gas):May form explosive dust-air mixture during processing, han-
dling or other means.Flammability (liquids):No data available



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flamn	nability limit			
	er explosion limit / Lower nability limit	:	No data available	9
Vapo	ur pressure	:	No data available	9
Relat	ive vapour density	:	No data available	9
Relat	ive density	:	No data available	9
Dens	ity	:	No data available	9
	bility(ies) /ater solubility	:	No data available	9
	ion coefficient: n- ol/water	:	Not applicable	
	ignition temperature	:	No data available	9
Deco	mposition temperature	:	No data available	9
Visco Vi	osity scosity, kinematic	:	No data available	9
Explo	osive properties	:	Not explosive	
Oxidi	zing properties	:	The substance o	r mixture is not classified as oxidizing.
	cle characteristics cle size	:	No data available	

Section 10: Stability and reactivity

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

Section 11: Toxicological information

Information on likely routes of	:	Inhalation
exposure		Skin contact



Dapton	nycin Injectior	n For	mulation	-	
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			Ingestion Eye contact		
	e toxicity				
	lassified based on av	ailable	information.		
	corrosion/irritation lassified based on av	ailable	information.		
	ponents:				
	omycin:				
Speci	ies	:	Rabbit		
Resu	lt	:	Mild skin irritati	n	
Serio	ous eye damage/eye	irritati	ion		
Not c	lassified based on av	ailable	information.		
<u>Com</u>	ponents:				
-	omycin:				
Speci Resu		:	Rabbit Mild eye irritatio	on	
			·		
Resp	iratory or skin sens	itisatio	on		
	sensitisation		information		
	lassified based on av		information.		
	iratory sensitisatior lassified based on av		information.		
Germ	n cell mutagenicity				
Not c	lassified based on av	ailable	information.		
<u>Com</u>	ponents:				
Dapte	omycin:				
Geno	toxicity in vitro	:	Test Type: Bac Result: negative	terial reverse mutation assay (AME e	S)
			Test Type: Chr Result: negative	omosome aberration test in vitro e	
				tro mammalian cell gene mutation t ouse lymphoma cells e	est
				A damage and repair, unscheduled nalian cells (in vitro) e	DNA sy
Geno	toxicity in vivo	:	Test Type: Mar	nmalian erythrocyte micronucleus te	est (in v





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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 develop- : ment	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:

	muscle, Kidney, Nervous system May cause damage to organs through prolonged or repeated	
		exposure.



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Repeated dose toxicity

Components:	
Daptomycin:SpeciesNOAELLOAELLOAELApplication RouteExposure timeTarget 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: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.

Experience with human exposure

Components:

Daptomycin: General Information

: Symptoms: Rash, Diarrhoea, vaginitis

Section 12: Ecological information

Toxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available



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	lity in soil ata available		
Othe	Other adverse effects		
No da	ata available		
Section 1	3: Disposal considera	tions	
Dispo	osal methods		
Wast	e from residues	•	of waste into sewer. ccordance with local regulations.
Conta	aminated packaging	: Empty containe dling site for re	ers should be taken to an approved waste han- cycling or disposal. e specified: Dispose of as unused product.

: Not applicable

Section 14: Transport information

International Regulations

UNRTDG			
UN number			
UN proper shipp			
Tuesday and barren			

UN proper shipping name:Not applicableClass:Not applicableSubsidiary risk:Not applicablePacking group:Not applicableLabels:Not applicablePacking instruction (cargo:Not applicableaircraft):Not applicablePacking instruction (passenger aircraft):Not applicableIMDG-Code::Not applicableUN number:Not applicableClass:Not applicableSubsidiary risk:Not applicablePacking group:Not applicableLabels:Not applicableEmS Code:Not applicable	UN proper shipping name Transport hazard class(es) Subsidiary risk Packing group Labels Environmentally hazardous		Not applicable Not applicable Not applicable Not applicable Not applicable no
UN number:Not applicableUN proper shipping name:Not applicableClass:Not applicableSubsidiary risk:Not applicablePacking group:Not applicableLabels:Not applicableEmS Code:Not applicable	UN/ID No. UN proper shipping name Class Subsidiary risk Packing group Labels Packing instruction (cargo aircraft) Packing instruction (passen-	•	Not applicable Not applicable Not applicable Not applicable
	UN number UN proper shipping name Class Subsidiary risk Packing group Labels EmS Code		Not applicable Not applicable

Transport in bulk according to IMO instruments

Not applicable for product as supplied.



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Special precautions for user

Not applicable

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 subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.
Environmental Protection and Management Act and : Not applicable
Environmental Protection and Management (Hazard-ous 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

Section 16: Other information

Revision Date	:	06.04.2024
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-

SAFETY DATA SHEET



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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