



Version 4.2	Revision Date: 06.04.2024		S Number:)783-00018	Date of last issue: 30.09.2023 Date of first issue: 02.05.2016			
SECTION	1: IDENTIFICATION						
Produ	uct name	:	Daptomycin In	jection Formulation			
Manu	ufacturer or supplier'	s deta	ils				
Com	pany	:	MSD				
Addre	Address			evel 1/26 Talavera Rd rk NSW, Australia 2113			
Telep	Telephone		1 800 033 461				
Emer	rgency telephone num	ber :	r : Poisons Information Centre: Phone 13 11 26				
E-ma	il address	:	EHSDATAST	EWARD@msd.com			
Reco	ommended use of the	chem	ical and restric	ctions on use			
Reco	mmended use	:	Pharmaceutic	al			
Restr	rictions on use	:	Not applicable				
0-0-101							
SECTION	2. HAZARDS IDENT	FICAT	ION				
GHS	Classification						
•	ific target organ toxicit		Category 2 (m	uscle, 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	:	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 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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

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

SECTION 4. FIRST AID 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 eye contact	:	If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
If swallowed	:	
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.
Protection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment
Notes to physician	:	when the potential for exposure exists (see section 8). Treat symptomatically and supportively.

SECTION 5. FIREFIGHTING MEASURES

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



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	Hazard ucts	lous combustion prod-	:	Carbon oxides	
Specific extinguishing meth- ods		:	Use extinguishing measures that are appropriate to local cir- cumstances 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.		
	Specia for firef	l protective equipment ighters	:	In the event of fire Use personal prot	e, wear self-contained breathing apparatus. ective equipment.
SEC	CTION 6	ACCIDENTAL RELE	ASI	E MEASURES	
	Personal precautions, protec- tive equipment and emer- gency procedures		:		ective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).
	Environmental precautions		:	Retain and dispos	akage or spillage if safe to do so. e of contaminated wash water. should be advised if significant spillages
	Methods and materials for containment and cleaning up		:	tainer for disposal Avoid dispersal of with compressed Dust deposits sho es, as these may leased into the atr Local or national r posal of this mate employed in the c mine which regula Sections 13 and 1	dust in the air (i.e., clearing dust surfaces

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 Advice on safe handling	:	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 as-



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	giene measures	Keep contai Keep away Take precau Take care to environmen : If exposure flushing sys place. When using Wash conta The effectiv engineering appropriate industrial hy use of admi	to chemical is likely during typical use, provide eye tems and safety showers close to the working do not eat, drink or smoke. minated clothing before re-use. e operation of a facility should include review of controls, proper personal protective equipment, degowning and decontamination procedures, rgiene monitoring, medical surveillance and the nistrative controls.
	nditions for safe storage terials to avoid	perly labelled containers. Fordance with the particular national regulations. The with the following product types: The agents	

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis		
		exposure)	concentration			
Daptomycin	103060-53-3	TWA	800 µg/m3 (OEB 2)	Internal		
Engineering measures	compound. All engineer design and	ing controls shou	ntrols to minimize expo uld be implemented by rdance with GMP prin nd the environment.	/ facility		
Personal protective equip	ment					
Respiratory protection	sure assess	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.				
Filter type Hand protection	: Particulates	type	e			
Material	: Chemical-re	Chemical-resistant gloves				
Eye protection	If the work e mists or aer Wear a face	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty condit mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is potential for direct contact to the face with dusts, mists,				



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Skin	and body protection	:	aerosols. Work uniform or la	aboratory coat.
SECTION	N 9. PHYSICAL AND CHI	EMI		S
Арр	earance	:	lyophilised cake	
Colo	bur	:	light brown	
Odo	ur	:	No data available	9
Odo	ur Threshold	:	No data available	9
pН		:	4.5 - 5	
Melt	ing point/freezing point	:	No data available	9
Initia rang	al boiling point and boiling le	:	No data available	9
Flas	h point	:	Not applicable	
Eva	poration rate	:	No data available	9
Flan	nmability (solid, gas)	:	May form explosi dling or other me	ive dust-air mixture during processing, han- ans.
Flan	nmability (liquids)	:	No data available	9
	er explosion limit / Upper mability limit	:	No data available	9
	er explosion limit / Lower mability limit	:	No data available	9
Vap	our pressure	:	No data available	9
Rela	tive vapour density	:	No data available	9
Rela	tive density	:	No data available	9
Den	sity	:	No data available	9
	bility(ies) Vater solubility	:	No data available	9
	ition coefficient: n-	:	Not applicable	
	nol/water b-ignition temperature	:	No data available	9
Dec	omposition temperature	:	No data available	9
Visc	osity			

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	Viscosity, kinematic	:	No data available)
	Explosive properties	:	Not explosive	
	Oxidizing properties	:	The substance o	mixture is not classified as oxidizing.
	Particle characteristics Particle size	:	No data available)
SEC	TION 10. STABILITY AND RE	EAC	ΤΙVITY	
	Reactivity	:	Not classified as	a reactivity hazard.
	Chemical stability	:	Stable under nor	mal conditions.
	Possibility of hazardous reac- tions	:		ve dust-air mixture during processing, han-
	uons		dling or other me Can react with st	rong oxidizing agents.
	Conditions to avoid	:	Heat, flames and	
	Incompatible materials		Avoid dust forma Oxidizing agents	uon.
	Hazardous decomposition products	:		composition products are known.
SEC	TION 11. TOXICOLOGICAL I			
SEC	TION TI. TOXICOLOGICAL I	NFC		
	Exposure routes	:	Inhalation	
			Skin contact	
			Ingestion Eye contact	
	A auto toviaitu		Lyc contact	
	Acute toxicity Not classified based on availa	blo	information	
		DIE		
	Skin corrosion/irritation Not classified based on availa	ble	information.	
	Components:			
	Daptomycin:			
	Species	:	Rabbit	
	Result	:	Mild skin irritation	
	.			
	Serious eye damage/eye irri			
	Not classified based on availa	ble	information.	
	<u>Components:</u>			
	Daptomycin:			
	Species	:	Rabbit	
	Result	:	Mild eye irritation	
			6 / 12	
			0/12	



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Resp	iratory or skin sens	itisation	
-	sensitisation lassified based on av	ailable information.	
-	iratory sensitisation lassified based on av		
Chro	nic toxicity		
	a cell mutagenicity lassified based on av	ailable information.	
Com	ponents:		
-	omycin: toxicity in vitro	: Test Type: Bac Result: negativ	cterial reverse mutation assay (AMES) e
		Test Type: Chr Result: negativ	omosome aberration test in vitro e
			itro mammalian cell gene mutation test nouse lymphoma cells e
			A damage and repair, unscheduled DNA syn- nalian cells (in vitro) e
Geno	toxicity in vivo	cytogenetic as Species: Mous	e ute: Intraperitoneal injection
		mammalian live Species: Hams	ster ute: Intraperitoneal injection

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.



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Com	oonents:				
Dapte	omycin:				
Effect	ts on fertility	Species: Rat Application Re Fertility: NOA	rtility/early embryonic development oute: Intravenous injection EL: 150 mg/kg body weight ects on fertility		
Effects on foetal develop- ment		Species: Rat Application Re Developments	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		
		Species: Rab Application Re Development	nbryo-foetal development bit oute: Intravenous injection al Toxicity: NOAEL: 75 mg/kg body weight nificant 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	:	Dog
NOAEL	:	20 mg/kg
LOAEL	:	40 mg/kg
Application Route	:	Intravenous
Exposure time	:	3 Months
Target Organs	:	Skeletal muscle
Species NOAEL Application Route Exposure time Remarks		Monkey 10 mg/kg Intravenous 1 Months No significant adverse effects were reported



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Expo Targe Symp Spec LOAE Applie Expo Targe Not c Expe	cation Route sure time et Organs otoms EL cation Route sure time et Organs ration toxicity lassified based on ava rience with human e	: muscle twitching : Juvenile dog : 50 mg/kg : Intravenous : 28 Days : Skeletal muscle	, Nervous system
	ponents:		
Dant	omvcin		
-	omycin: ral Information	: Symptoms: Ras	h, Diarrhoea, vaginitis
Gene SECTION Ecote No da Persi	-	IFORMATION	h, Diarrhoea, vaginitis
Gene SECTION Ecoto No da Persi No da Bioad	ata available istence and degrada	IFORMATION	h, Diarrhoea, vaginitis
Gene SECTION Ecoto No da Persi No da Bioao No da Mobi	Information 12. ECOLOGICAL IN oxicity ata available stence and degrada ata available ccumulative potentia	IFORMATION	h, Diarrhoea, vaginitis

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 han- dling site for recycling or disposal.
		If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations



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UNR	TDG			
	number	:	Not applicable	
	er shipping name	:	Not applicable	
Clas		:	Not applicable	
	sidiary risk	:	Not applicable	
	king group	÷	Not applicable	
Labe	ronmentally hazardous	÷	Not applicable	
		·	no	
	A-DGR			
	D No.	:	Not applicable	
	er shipping name	:	Not applicable	
Clas	-	:	Not applicable	
	sidiary risk	÷	Not applicable	
Labe	king group	÷	Not applicable Not applicable	
	king instruction (cargo	:	Not applicable	
aircra	.	•	Not applicable	
	king instruction (passen-	:	Not applicable	
	aircraft)	•	not applicable	
•	G-Code			
	number		Not applicable	
	er shipping name	:	Not applicable	
Clas			Not applicable	
	sidiary risk	÷	Not applicable	
	king group	:	Not applicable	
Labe		:	Not applicable	
EmS	Code	:	Not applicable	
Marii	ne pollutant	:	Not applicable	
Tran	sport in bulk according	ot r	Annex II of MAR	POL 73/78 and the IBC Code
an		,		

Not applicable for product as supplied.

National Regulations

ADG UN number Proper shipping name Class Subsidiary risk Packing group Labels		Not applicable Not applicable Not applicable Not applicable Not applicable
Hazchem Code	:	Not applicable

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

Therapeutic Goods (Poisons : No poison schedule number allocated (Please use the original



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Standa	ard) Instrument		•		specific uses, specific conditions or ht apply for this chemical)
Prohib	Prohibition/Licensing Requirement		nts	:	There is no applicable prohibition, authorisation and restricted use requirements, including for carcino- gens referred to in Schedule 10 of the model WHS Act and Regula- tions.
The co	omponents of this pr	odu	ct are reported in	the fol	lowing inventories:
AICS		:	not determined		
DSL		:	not determined		
IECSC	;	:	not determined		

SECTION 16: ANY OTHER RELEVANT INFORMATION

Further information

Revision Date Sources of key data used to compile the Safety Data Sheet	:	06.04.2024 Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- 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 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, Bioaccumu-

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lative 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.

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