



Version 3.1	Revision Date: 2023/09/30		S Number:)792-00017	Date of last issue: 2023/04/04 Date of first issue: 2016/05/02
1. PRODU	ICT AND COMPANY IDI	ENT	IFICATION	
Produ	uct name	:	Daptomycin I	njection Formulation
Manu	Ifacturer or supplier's d	letai	ils	
Comp	bany	:	MSD	
Addre	ess	:	126 E. Lincol Rahway, Nev	n Avenue v Jersey U.S.A. 07065
Telep	hone	:	908-740-400)
Emer	gency telephone number	• :	1-908-423-60	00
E-ma	il address	:	EHSDATAST	EWARD@msd.com
Reco	mmended use of the ch	nem	ical and restri	ctions on use
	mmended use ictions on use	:	Pharmaceution Not applicabl	
2 HA7AR	DS 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.
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
	Specific target organ toxicity - repeated exposure (Dermal) GHS label elements Hazard pictograms Signal word Hazard statements	Specific target organ toxicity - repeated exposure (Dermal):GHS label elements Hazard pictograms:Signal word:Hazard statements:



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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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture	:	Mixture
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Components

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

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 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	:	May cause damage to organs through prolonged or repeated
and effects, both acute and		exposure in contact with skin.
delayed		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.
5. FIREFIGHTING MEASURES		
5. FIREFIGHTING MEASURES		
Suitable extinguishing media	:	Water spray
Suitable extinguishing media	•	Alcohol-resistant foam
		Carbon dioxide (CO2) Dry chemical
Linguitable extinguishing		None known.
Unsuitable extinguishing media	·	

Specific hazards during fire- : Avoid generating dust; fine dust dispersed in air in sufficient



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fighting			potential dust exp	nd in the presence of an ignition source is a losion hazard. bustion products may be a hazard to health.	
	Hazard ucts	ous combustion prod-	:	Carbon oxides	
	Specific extinguishing meth- ods		:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
	Special for firefi	protective equipment ghters	:		e, wear self-contained breathing apparatus. ective equipment.
6. A	CCIDEN	ITAL RELEASE MEAS	SUF	RES	
	tive equ	al precautions, protec- ipment and emer- procedures	:		ective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).
	Environ	mental precautions	:	Retain and dispos	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages
		s and materials for ment 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
7. H	ANDLIN	IG AND STORAGE			
	Local/T	cal measures	:	causing an explose Provide adequate and bonding, or in Use only with ade	precautions, such as electrical grounding nert atmospheres. quate ventilation.
	Advice	on safe handling	:	Do not get on skir Do not breathe du Do not swallow.	



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	tions for safe storage ials to avoid	practice, based of sessment Minimize dust ge Keep container of Keep away from Take precautiona Take care to pre- environment. : Keep in properly Store in accordat	lance with good industrial hygiene and safety on the results of the workplace exposure as- eneration and accumulation. closed when not in use. heat and sources of ignition. ary measures against static discharges. vent spills, waste and minimize release to the labelled containers. nce with the particular national regulations. the following product types:

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis				
Daptomycin	103060-53-3	TWA	800 µg/m3 (OEB 2)	Internal				
Engineering measures :	compound. All engineerin design and op	g controls should	rols to minimize expo d be implemented by dance with GMP princ d the environment.	facility				
Personal protective equipmer	nt							
Respiratory protection : Filter type : Hand protection	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type							
Material	Chemical-resi	Chemical-resistant gloves						
Eye protection : Skin and body protection : Hygiene measures :	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. Work uniform or laboratory coat. If exposure to chemical is likely during typical use, provide							
	eye flushing s ing place. When using d	eye flushing systems and safety showers close to the work-						

Components with workplace control parameters



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			engineering cont appropriate dego	eration of a facility should include review of rols, proper personal protective equipment, owning and decontamination procedures, e monitoring, medical surveillance and the ative controls.
9. PHYSIC	CAL AND CHEMICAL P	ROF	PERTIES	
Арре	earance	:	lyophilised cake	
Color	ur	:	light brown	
Odou	ır	:	No data availab	le
Odou	ur Threshold	:	No data availab	le
pН		:	4.5 - 5	
Melti	ng point/freezing point	:	No data availab	le
Initial range	l boiling point and boiling e	:	No data availab	le
Flash	n point	:	Not applicable	
Evap	oration rate	:	No data availab	le
Flam	mability (solid, gas)	:	May form explosed dling or other m	sive dust-air mixture during processing, han- eans.
Flam	mability (liquids)	:	No data availab	le
	er explosion limit / Upper nability limit	:	No data availab	le
	er explosion limit / Lower nability limit	:	No data availab	le
Vapo	our pressure	:	No data availab	e
Relat	tive vapour density	:	No data availab	e
Relat	tive density	:	No data availab	le
Dens	iity	:	No data availab	le
	bility(ies) /ater solubility	:	No data availab	le
octar	tion coefficient: n- nol/water	:	Not applicable No data availab	
Auto	-ignition temperature	•	ino uala availad	

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De	ecomposition temperature	: No data availa	ble
Vi	scosity Viscosity, kinematic	: No data availa	able
E>	plosive properties	: Not explosive	
O	xidizing properties	: The substance	e or mixture is not classified as oxidizing.
Pa	article size	: No data availa	ble

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	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials Hazardous decomposition products	:	Oxidizing agents No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of	:	Inhalation
exposure		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.



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Com	oonents:		
Dapto	omycin:		
Speci Resul	es	: Rabbit : Mild eye irritati	on
-	iratory or skin sens	itisation	
	sensitisation lassified based on av	ailable information	
	iratory sensitisatior		
-	lassified based on av		
Germ	cell mutagenicity		
Not c	lassified based on av	ailable information.	
Com	ponents:		
-	omycin:		
Geno	toxicity in vitro	: Test Type: Bao Result: negativ	cterial reverse mutation assay (AMES) /e
		Test Type: Chi Result: negativ	romosome aberration test in vitro /e
			vitro mammalian cell gene mutation test nouse lymphoma cells ve
			A damage and repair, unscheduled DNA syn- malian cells (in vitro) /e
Geno	toxicity in vivo	cytogenetic as Species: Mous	se ute: Intraperitoneal injection
		mammalian liv 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	ponents:		
Dapte	omycin:		
Effec	ts on fertility	Species: Rat Application Ro Fertility: NOA	rtility/early embryonic development oute: Intravenous injection EL: 150 mg/kg body weight ects on fertility
Effec ment	ts on foetal develop-	Species: Rat Application Ro Developmenta	nbryo-foetal development oute: Intravenous injection al Toxicity: NOAEL: 75 mg/kg body weight inificant adverse effects were reported
		Species: Rabl Application Ro Developmenta	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	cation Route sure time et Organs otoms	: Dog : Intravenous : 28 Days : Skeletal musc : muscle twitchi : Juvenile dog	le, Nervous system ng
LÖAE Applio Expos		: 50 mg/kg : Intravenous : 28 Days	le, Nervous system
Not c	ration toxicity lassified based on avai rience with human ex		
Dapte	ponents: omycin: eral Information	: Symptoms: Ra	ash, Diarrhoea, vaginitis
12. ECOL	OGICAL INFORMATIC)N	
	oxicity ata available		
	stence and degradab ata available	ility	
	ccumulative potential ata available		
	lity in soil ata available		
	r adverse effects ata available		
13. DISPC	SAL CONSIDERATIO	NS	
-	osal methods		
Waste	e from residues		e of waste into sewer. accordance with local regulations.
Conta	aminated packaging	: Empty contain dling site for re	ers should be taken to an approved waste han- ecycling or disposal. e specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations



ersion 1	Revision Date: 2023/09/30	SDS Number: 650792-00017	Date of last issue: 2023/04/04 Date of first issue: 2016/05/02
Prope Class Subsi	umber er shipping name diary risk ng group	 Not applicable 	
Class Subsi Packi Label Packi aircra Packi) No. er shipping name diary risk ng group s ng instruction (cargo	 Not applicable 	
UN nu Prope Class Subsi Packi Label EmS	diary risk ng group s	 Not applicable 	
	sport in bulk according		POL 73/78 and the IBC Code
Spec	ial precautions for use		

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No.	74 of 2001 on the	Management of I	Hazardous and 1	oxic Sub-
stances				

Hazardous substances approved for use	
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: Not applicable





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Prohibited su	Ibstances		: Not applicable
Restricted su	Ibstances		: Not applicable
Regulation of Materials	of the Ministry o	f Trade No. 7 of 20	22 on Distribution and Control of Hazardo
Type of haza control, Anne		subject to distribution	n and : Not applicable
Type of haza control, Anne	rdous materials s ex II	subject to distribution	n and : Not applicable
		subject to distribution	n and : Not applicable
control, Anne	ex II		
control, Anne	ex II		in the following inventories:
Control, Anne	ex II	duct are reported i	in the following inventories:
The compor	ex II	duct are reported i : not determined	in the following inventories:
The compor AICS DSL	ex II	duct are reported i : not determined : not determined	in the following inventories:
The compor AICS DSL	ex II	duct are reported i : not determined : not determined	in the following inventories:
The compor AICS DSL IECSC	ex II nents of this pro	duct are reported i : not determined : not determined	in the following inventories:
The compor AICS DSL IECSC OTHER INFO	ex II nents of this pro RMATION	duct are reported i : not determined : not determined : not determined	in the following inventories:
The compor AICS DSL IECSC OTHER INFO Revision Dat Further info	e RMATION e rmation ey data used to	duct are reported i : not determined : not determined : not determined : 2023/09/30 : Internal technic	an the following inventories:
The compor AICS DSL IECSC OTHER INFO Revision Dat Further info Sources of k compile the S	e RMATION e rmation ey data used to	duct are reported i : not determined : not determined : not determined : 2023/09/30 : Internal technic eChem Portal s	an the following inventories:

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

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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.

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