

ersion 2	Revision Date: 2024/09/28		S Number: 974-00022	Date of last issue: 2023/09/26 Date of first issue: 2014/11/03
PRODU	ICT AND COMPANY IDE	ENT	IFICATION	
Produ	uct name	:	Ertapenem Fo	ormulation
Manu	facturer or supplier's d	etai	ils	
Comp	bany	:	MSD	
Addre	ess	:	126 E. Lincolr Rahway, New	n Avenue v Jersey U.S.A. 07065
Telep	hone	:	908-740-4000)
Emer	gency telephone number	:	1-908-423-60	00
E-mai	il address	:	EHSDATAST	EWARD@msd.com
Reco	mmended use of the ch	nem	ical and restri	ctions on use
	mmended use ictions on use	:		

GHS Classification Respiratory sensitisation	Category 1	
Short-term (acute) aquatic hazard	Category 1	
Long-term (chronic) aquatic hazard	Category 2	
GHS label elements		
Hazard pictograms		
Signal word	Danger	
Hazard statements	H334 May cause allergy or asthma symptoms o difficulties if inhaled. H400 Very toxic to aquatic life. H411 Toxic to aquatic life with long lasting effect	-
Precautionary statements	Prevention: P261 Avoid breathing dust.	



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P273 Avoid release to the environment. P284 Wear respiratory protection.

Response:

P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor. P391 Collect spillage.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Ertapenem	153773-82-1	>= 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.
		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.
		If not breathing, give artificial respiration.
		If breathing is difficult, give oxygen.
		Get medical attention.
In case of skin contact	:	Wash with water and soap.
		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	:	May cause allergy or asthma symptoms or breathing difficul- ties if inhaled.
delayed		Excessive exposure may aggravate preexisting asthma and



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		ion of first-aiders o physician	:	tive airways dysfu Contact with dust the skin. Dust contact with First Aid respond and use the reco when the potentia	disorders (e.g. emphysema, bronchitis, reac- unction syndrome). can cause mechanical irritation or drying of the eyes can lead to mechanical irritation. ers should pay attention to self-protection, mmended personal protective equipment al for exposure exists (see section 8). ically and supportively.
5. FIR	REFIGI	HTING MEASURES			
S	Suitabl	e extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide ((Dry chemical	
	Jnsuita nedia	able extinguishing	:	None known.	
	Specific ighting	c hazards during fire-	:	concentrations, a potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a plosion hazard. bustion products may be a hazard to health.
	Hazardous combustion prod- ucts		:	Carbon oxides Metal oxides	
	Specifi ods	c extinguishing meth-	:	cumstances and Use water spray	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do
		l protective equipment ighters	:		e, wear self-contained breathing apparatus. tective equipment.
6. AC	CIDEN	NTAL RELEASE MEAS	SUF	RES	
ti	ive equ	al precautions, protec- uipment and emer- procedures	:	Follow safe hand	tective equipment. ling advice (see section 7) and personal pro- t recommendations (see section 8).
E	Enviror	nmental precautions	:	Retain and dispo	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages

Methods and materials for : Surround spill with absorbents and place a damp covering

cannot be contained.



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conta	inment and cleaning up	Add excess li Soak up with Avoid dispers with compres Dust deposits es, as these r leased into th Clean up rem bent. Local or natio posal of this r employed in t mine which re Sections 13 a	to minimise entry of the material into the air. quid to allow the material to enter into solution. inert absorbent material. al of dust in the air (i.e., clearing dust surfaces sed air). a should not be allowed to accumulate on surfac- may form an explosive mixture if they are re- e atmosphere in sufficient concentration. aining materials from spill with suitable absor- nal regulations may apply to releases and dis- naterial, as well as those materials and items he cleanup of releases. You will need to deter- egulations are applicable. and 15 of this SDS provide information regarding or national requirements.
7. HANDL	ING AND STORAGE		
Local	nical measures	 causing an experience Provide adeq and bonding, Use only with Do not breath Do not swallo Avoid contact Avoid prolong Handle in acco practice, base sessment Keep containe Already sensit to asthma, all should consut tory irritants of Minimize dust Keep containe Keep away fre Take precauti 	uate precautions, such as electrical grounding or inert atmospheres. adequate ventilation. e dust. w. w. with eyes. ged or repeated contact with skin. cordance with good industrial hygiene and safety ed on the results of the workplace exposure as- er tightly closed. tised individuals, and those susceptible ergies, chronic or recurrent respiratory disease, It their physician regarding working with respira-
Cond	litions for safe storage	: Keep in prope Keep tightly c	erly labelled containers. losed. rdance with the particular national regulations.
Mate	rials to avoid		with the following product types:



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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis	
Ertapenem	153773-82-1	TŴA	0.15 mg/m3 (OEB 2)	Internal	
	Further information: RSEN				

Engineering measures	Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are de- signed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).	
Personal protective equipme		
Respiratory protection Filter type	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type	
Hand protection		
Material	Chemical-resistant gloves	
Remarks	Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub- stance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.	
Eye protection	Wear the following personal protective equipment: Safety goggles	
Skin and body protection Hygiene measures	Skin should be washed after contact. If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the work- ing place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.	

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	white
Odour	:	No data available



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Odo	ur Threshold	:	No data available	
pН		:	No data available)
Melt	ing point/freezing point	:	No data available	2
Initia rang	al boiling point and boiling le	:	No data available	9
Flas	h point	:	No data available	9
Eva	poration rate	:	No data available	9
Flam	nmability (solid, gas)	:	May form explos dling or other me	ive dust-air mixture during processing, han- ans.
Flam	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-	:	No data available	9
	nol/water -ignition temperature	:	No data available	9
Dec	omposition temperature	:	No data available	9
	osity /iscosity, dynamic	:	No data available	9
V	iscosity, kinematic	:	No data available	9
Expl	osive properties	:	Not explosive	
Oxid	lizing properties	:	The substance o	r mixture is not classified as oxidizing.



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Mole	cular weight	:	No data availa	ble
	cle characteristics cle size	:	No data availa	ble
IO. STAE	ILITY AND REACTIVITY	,		
Chei	ctivity nical stability ibility of hazardous reac-	:	Stable under n May form expl dling or other r	as a reactivity hazard. formal conditions. osive dust-air mixture during processing, han- neans. strong oxidizing agents.
	ditions to avoid npatible materials	:	Heat, flames a Avoid dust forr Oxidizing ager	nation.
	ardous decomposition	:		decomposition products are known.
	COLOGICAL INFORMAT	101	N	
1. 10/1				
	mation on likely routes of sure		Inhalation Skin contact Ingestion Eye contact	
Infor expc Acut	-	:	Skin contact Ingestion Eye contact	
Infor expo Acut Not o	sure e toxicity	:	Skin contact Ingestion Eye contact	
Infor expo Acut Not o <u>Com</u> Erta	sure e toxicity classified based on availa	: ble	Skin contact Ingestion Eye contact	> 500 mg/kg
Infor expo Acut Not o <u>Com</u> Erta Acut	sure te toxicity classified based on availa ponents: penem:	: ble :	Skin contact Ingestion Eye contact information. LD50 (Mouse): LD50 (Mouse):	
Infor expo Acut Not o <u>Com</u> Erta Acut	sure te toxicity classified based on availa ponents: penem: e oral toxicity e toxicity (other routes of	: ble :	Skin contact Ingestion Eye contact information. LD50 (Mouse): Application Rou LD50 (Rat): > 7	> 700 mg/kg ute: Intravenous
Infor expo Acut Not o Erta Acut Acut adm	sure te toxicity classified based on availa ponents: penem: e oral toxicity e toxicity (other routes of	: ble :	Skin contact Ingestion Eye contact information. LD50 (Mouse): Application Rou LD50 (Rat): > 7 Application Rou	> 700 mg/kg ute: Intravenous '00 mg/kg
Infor expo Acut Not o Erta Acut Acut Skin Not o	sure te toxicity classified based on availa ponents: penem: e oral toxicity e toxicity (other routes of nistration) corrosion/irritation	: ble :	Skin contact Ingestion Eye contact information. LD50 (Mouse): Application Rou LD50 (Rat): > 7 Application Rou	> 700 mg/kg ute: Intravenous '00 mg/kg

Serious eye damage/eye irritation

Not classified based on available information.



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<u>Com</u>	ponents:		
Ertap	enem:		
Speci Resu		: Rabbit : Mild eye	irritation
Resp	iratory or skin sens	itisation	
	sensitisation lassified based on av	ailable informatio	ın.
•	iratory sensitisatior cause allergy or asthr		breathing difficulties if inhaled.
Com	ponents:		
-	enem: sure routes		n (dust/mist/fume)
Asses	ssment		
Resu	lt	animal te : positive	
Resu Germ Not c		animal te : positive	esting
Resu Germ Not c <u>Com</u>	lt n cell mutagenicity lassified based on av	animal te : positive	esting
Resu Germ Not c <u>Com</u> J Ertap	lt n cell mutagenicity lassified based on av ponents:	animal te : positive railable informatio	e: Bacterial reverse mutation assay (AMES)
Resu Germ Not c <u>Com</u> J Ertap	It n cell mutagenicity lassified based on av ponents: penem:	animal te : positive railable informatio : Test Typ Result: n Test Typ	e: Alkaline elution assay tem: rat hepatocytes
Resu Germ Not c <u>Com</u> J Ertap	It n cell mutagenicity lassified based on av ponents: penem:	animal te : positive railable informatio : Test Typ Result: n Test Typ Test syst Result: n	e: Bacterial reverse mutation assay (AMES) legative e: Alkaline elution assay tem: rat hepatocytes legative e: Chromosomal aberration tem: Chinese hamster ovary cells
Resu Germ Not c <u>Com</u> Ertap	It n cell mutagenicity lassified based on av ponents: penem:	animal te : positive railable informatio : Test Typ Result: n Test Typ Test syst Result: n Test Typ Test syst Result: n	e: Bacterial reverse mutation assay (AMES) legative e: Alkaline elution assay tem: rat hepatocytes legative e: Chromosomal aberration tem: Chinese hamster ovary cells legative e: In vitro mammalian cell gene mutation test tem: human lymphoblastoid cells

Reproductive toxicity

Not classified based on available information.



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Com	ponents:		
Ertap	enem:		
Effect	ts on fertility	Species: Rat Application Ro Fertility: NOAE	
		Species: Mous Fertility: NOAE Result: No effe	e :L: 700
Effect ment	ts on foetal develop-	Developmenta	
		Developmenta Symptoms: Re	e ute: Intravenous injection I Toxicity: NOAEL: 350 mg/kg body weight duced body weight mechanism or mode of action may not be rele
	Γ - single exposure lassified based on ava	lable information.	
	F - repeated exposure lassified based on ava		
Repe	ated dose toxicity		
Com	ponents:		
Ertap	enem:		
Expo	EL cation Route sure time et Organs	: Rat : 2 mg/kg : Intravenous : 2 Weeks : Blood : The mechanisi mans.	m or mode of action may not be relevant in hι
Expo		: Rat : 60 mg/kg : Intravenous : 6 Months : Blood	



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Rema	rks	:	The mechanism c	or mode of action may not be relevant in hu-
Expos	L L ation Route ure time : Organs		mans. Monkey 360 mg/kg 500 mg/kg Intravenous 27 Weeks Liver, Kidney The mechanism of mans.	or mode of action may not be relevant in hu-
Aspira	ation toxicity			
Not cla	assified based on availa	ble	information.	
Exper	ience with human exp	osı	ire	
<u>Comp</u>	onents:			
Ertape Inhala Ingest	tion	:		use sensitisation by inhalation. noea, Nausea, Headache, vaginitis
Ecoto <u>Comp</u> Ertape	onents:			
-	y to fish	:	LC50 (Pimephale Exposure time: 96	s promelas (fathead minnow)): > 1,000 mg/l 5 h
	ty to daphnia and other cinvertebrates	:	EC50 (Daphnia m Exposure time: 48	nagna (Water flea)): > 500 mg/l 3 h
Toxicit plants	ty to algae/aquatic	:	EC50 (Pseudokiro mg/l Exposure time: 72 Method: OECD To	
			NOEC (Pseudokin mg/l Exposure time: 72 Method: OECD Te	
			EC50 (Anabaena Exposure time: 72 Method: OECD Te	
			NOEC (Anabaena Exposure time: 72	a flos-aquae): 0.13 mg/l 2 h

Disposal methods



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			Method: OECD	Fest Guideline 201
	tor (Acute aquatic tox-	:	1	
icity) Toxicit <u>y</u> icity)	y to fish (Chronic tox-	:	Exposure time: 3	lles promelas (fathead minnow)): 2.5 mg/l 32 d Fest Guideline 210
	y to daphnia and other c invertebrates (Chron- ity)	:	Exposure time: 2	magna (Water flea)): 82 mg/l 1 d Fest Guideline 211
Toxicity	y to microorganisms	:	EC10: 3.9 mg/l Exposure time: 3 Test Type: Resp	
Persis	tence and degradabili	ty		
Compo	onents:			
Ertape	enem:			
Biodeg	ıradability	:	Biodegradation: Exposure time: 2	
Stabilit	y in water	:	Degradation half	life (DT50): 15.3 d
Bioaco	cumulative potential			
Compo	onents:			
Ertape Partitio octano	n coefficient: n-	:	log Pow: -2.22	
	ty in soil a available			
	adverse effects a available			

:	Do not dispose of waste into sewer.
	Dispose of in accordance with local regulations.
:	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.





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14. TRANSPORT INFORMATION

International Regulations

UNRTDG		
UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ertapenem)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes
IATA-DGR		
UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Ertapenem)
Class	:	9
Packing group	:	
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passen- ger aircraft)	:	956
Environmentally hazardous	:	yes
IMDG-Code		
UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
		(Ertapenem)
Class	÷	9
Packing group	÷	
Labels	÷	9
EmS Code	:	F-A, S-F
Marine pollutant	•	yes

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

Not applicable for product as supplied.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.



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15. REGULATORY INFORMATION

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
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Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use	:	Not applicable
Prohibited substances	:	Not applicable
Restricted substances	:	Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and : Not applicable control, Annex I

Type of hazardous materials subject to distribution and : Not applicable control, Annex II

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

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

16. OTHER INFORMATION

Revision Date	:	2024/09/28
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	:	yyyy/mm/dd

Full text of other abbreviations



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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 - 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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