

Ertapenem Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	9371366-00008	Date of first issue: 27.08.2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1	Product identifier Trade name	:	Ertapenem Formulation
1.2	Relevant identified uses of th	ne s	ubstance or mixture and uses advised against
	Use of the Sub- stance/Mixture		Pharmaceutical
	Recommended restrictions on use	:	Not applicable
1.3	Details of the supplier of the	saf	ety data sheet
	Company	:	MSD 120 Moorgate EC2M 6UR London, United Kingdom
	Telephone	:	+44 (0) 2081548000
	E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification

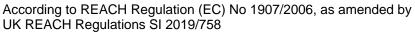
2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Respiratory sensitisation, Category 1	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Short-term (acute) aquatic hazard, Cate- gory 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Cat- egory 2	H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)





Ertapenem Formulation

Version 4.3	Revision Date: 28.09.2024	-	SDS Number: 371366-00008	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021
Hazard pictograms		:		¥2
Signa	al word	:	Danger	•
Haza	rd statements	:		May cause allergy or asthma symptoms or breath- ing difficulties if inhaled.
				Very toxic to aquatic life with long lasting effects.
Preca	autionary statements	:	Prevention:	
				Avoid breathing dust. Avoid release to the environment.
				Wear respiratory protection.
			Response:	
			P304 + P340	· · · · · · · · · · · · · · · · · · ·
			P342 + P311	keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.
				Collect spillage.

Hazardous components which must be listed on the label: Ertapenem

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Ertapenem	153773-82-1	Resp. Sens. 1; H334 Aquatic Acute 1; H400 Aquatic Chronic 2; H411 M-Factor (Acute aquatic toxicity): 1	>= 70 - < 90

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Ertapenem Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	9371366-00008	Date of first issue: 27.08.2021

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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. 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. 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). 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.

4.2 Most important symptoms and effects, both acute and delayed

Risks	: May cause allergy or asthma symptoms or breathing difficul- ties if inhaled.
	Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
	Contact with dust can cause mechanical irritation or drying of the skin.
	Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment	:	Treat symptomatically and supportively.
-----------	---	---

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Ertapenem Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	9371366-00008	Date of first issue: 27.08.2021

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.

5.2 Special hazards arising from the substance or mixture

5.2 Special nazards arising from	τηε	e substance or mixture
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 prod- ucts	:	Carbon oxides Metal oxides
5.3 Advice for firefighters		
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).		
6.2 Environmental precautions				
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. If spillage enters rivers or watercourses, inform the Environ- ment Agency (emergency telephone number 0800 807060).		

6.3 Methods and material for containment and cleaning up

Methods for cleaning up	:	Surround spill with absorbents and place a damp covering
		over the area to minimise entry of the material into the air.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Ertapenem Formulation

Version	Revision Date: 28.09.2024	SDS Number:	Date of last issue: 06.04.2024
4.3		9371366-00008	Date of first issue: 27.08.2021
		Soak up with in Avoid dispersal with compresse Dust deposits si es, as these ma leased into the a Clean up remain bent. Local or nationa posal of this ma employed in the mine which regu	id to allow the material to enter into solution. ert absorbent material. of dust in the air (i.e., clearing dust surfaces d air). hould not be allowed to accumulate on surfac- ty form an explosive mixture if they are re- atmosphere in sufficient concentration. hing materials from spill with suitable absor- al regulations may apply to releases and dis- terial, as well as those materials and items e cleanup of releases. You will need to deter- ulations are applicable. d 15 of this SDS provide information regarding mational requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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	afe handling :	Do not breathe dust.
		Do not swallow.
		Avoid contact with eyes.
		Avoid prolonged or repeated contact with skin.
		Handle in accordance with good industrial hygiene and safety
		practice, based on the results of the workplace exposure as-
		sessment
		Keep container tightly closed.
		Already sensitised individuals, and those susceptible
		to asthma, allergies, chronic or recurrent respiratory disease,
		should consult their physician regarding working with respira- tory irritants or sensitisers.
		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 contami-
		nated clothing before re-use.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage : Keep in properly labelled containers. Keep tightly closed.



Ertapenem Formulation

Version 4.3	Revision Date: 28.09.2024		DS Number: 371366-00008	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021
areas	and containers		Store in accorda	nce with the particular national regulations.
Advic	e on common storage	:	Do not store with the following product types: Strong oxidizing agents	
•	f ic end use(s) fic use(s)	:	No data available	

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits	i
dust of any kind	10 mg/m3 Value type (Form of exposure): TWA (Inhalable) Basis: GB EH40

4 mg/m3 Value type (Form of exposure): TWA (Respirable fraction) Basis: GB EH40

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

8.2 Exposure controls

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 designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

Personal protective equipment

Eye/face protection	:	Wear the following personal protective equipment: Safety goggles Equipment should conform to BS EN 166	
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	



Ertapenem Formulation

Version 4.3	Revision Date: 28.09.2024	SDS Number: 9371366-00008	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021
	and body protection iratory protection	glove manufa end of workda Skin should b If adequate lo sure assessm ommended gu	the aforementioned protective gloves with the cturer. Wash hands before breaks and at the ay. e washed after contact. cal exhaust ventilation is not available or expo- ient demonstrates exposures outside the rec- uidelines, use respiratory protection. ould conform to BS EN 143
Fil	ter type	: Particulates ty	vpe (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Information on basic physical	l an	
Appearance Colour	÷	powder white
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.
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	·	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Ertapenem Formulation

	evision Date: 8.09.2024		S Number: 71366-00008	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021		
	ty, dynamic ty, kinematic	:	No data available No data available Not explosive	-		
Oxidizing p				ostance or mixture is not classified as oxidizing.		
9.2 Other infor Flammabili Molecular v Particle siz	ity (liquids) weight	::	No data available No data available No data available	9		

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	 May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents.
10.4 Conditions to avoid	
Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.
10.5 Incompatible materials	
Materials to avoid	: Oxidizing agents
10.6 Hazardous decomposition	products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of	:	Inhalation
exposure		Skin contact
		Ingestion
		Eye contact

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Ertapenem Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	9371366-00008	Date of first issue: 27.08.2021

Application Route: Intravenous

Acute toxicity

Not classified based on available information.

Components:

Ertapenem:

Acute oral toxicity	:	LD50 (Mouse): > 500 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Mouse): > 700 mg/kg Application Route: Intravenous
		LD50 (Rat): > 700 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Ertapenem:

Species	:	Rabbit
Result	:	No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Ertapenem:

Species	:	Rabbit
Result	:	Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:

Ertapenem:	
------------	--

Exposure routes	:	inhalation (dust/mist/fume)
Assessment	:	Probability of respiratory sensitisation in humans based on
		animal testing
Result	:	positive

Germ cell mutagenicity

Not classified based on available information.



Ertapenem Formulation

rsion	Revision Date: 28.09.2024	SDS Number: 9371366-00008	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021
<u>Com</u>	oonents:		
Ertap	enem:		
-	toxicity in vitro	: Test Type: Bac Result: negative	terial reverse mutation assay (AMES) e
		Test Type: Alka Test system: ra Result: negative	
			omosomal aberration hinese hamster ovary cells e
			tro mammalian cell gene mutation test Iman lymphoblastoid cells Ə
Geno	toxicity in vivo	: Test Type: Micr Species: Mouse Result: negative	9
	lassified based on ava	ailable information.	
Ertap	enem:		
Effect	s on fertility	Species: Rat Application Rou Fertility: NOAEI Result: No effect ment were deter Test Type: Fert	: 700 mg/kg body weight cts on fertility and early embryonic develop cted. ility
		Species: Mouse Fertility: NOAEI Result: No effe	_: 700
Effect ment	s on foetal develop-	Developmental	
		Test Type: Dev Species: Mouse	

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Ertapenem Formulation

Version	Revision Date: 28.09.2024	SDS Number:	Date of last issue: 06.04.2024
4.3		9371366-00008	Date of first issue: 27.08.2021
			duced body weight mechanism or mode of action may not be rele-

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Ertapenem:

Species : LOAEL : Application Route : Exposure time : Target Organs : Remarks :	Rat 2 mg/kg Intravenous 2 Weeks Blood The mechanism or mode of action may not be relevant in hu- mans.
Species:LOAEL:Application Route:Exposure time:Target Organs:Remarks:	Rat 60 mg/kg Intravenous 6 Months Blood The mechanism or mode of action may not be relevant in hu- mans.
Species:NOAEL:LOAEL:Application Route:Exposure time:Target Organs:Remarks:	Monkey 360 mg/kg 500 mg/kg Intravenous 27 Weeks Liver, Kidney The mechanism or mode of action may not be relevant in hu- mans.

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Ertapenem:

Inhalation	:	Remarks: May cause sensitisation by inhalation.
Ingestion	:	Symptoms: Diarrhoea, Nausea, Headache, vaginitis

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Ertapenem Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	9371366-00008	Date of first issue: 27.08.2021

SECTION 12: Ecological information

12.1 Toxicity

Components:		
Ertapenem: Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 500 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 51 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 51 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		EC50 (Anabaena flos-aquae): 0.23 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Anabaena flos-aquae): 0.13 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic tox- icity)	:	1
Toxicity to microorganisms	:	EC10 : 3.9 mg/l Exposure time: 3 h Test Type: Respiration inhibition
Toxicity to fish (Chronic tox- icity)	:	NOEC: 2.5 mg/l Exposure time: 32 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 82 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758

SDS Number:



Date of last issue: 06.04.2024

Ertapenem Formulation

Revision Date:

Version

			Date of first issue: 27.08.2021
istence and degradabi	lity		
ponents:			
benem:			
egradability	:	Biodegradation Exposure time:	dily biodegradable. : 4.7 % 28 d Test Guideline 301B
lity in water	:	Degradation ha	lf life (DT50): 15.3 d
ccumulative potential			
ponents:			
ion coefficient: n-	:	log Pow: -2.22	
•			
llts of PBT and vPvB a	sse	ssment	
	:	to be either per very persistent	/mixture contains no components considered sistent, bioaccumulative and toxic (PBT), or and very bioaccumulative (vPvB) at levels of
r adverse effects			
uct:			
crine disrupting poten-	:	ered to have er	/mixture does not contain components consid- docrine disrupting properties for environment K REACH Article 57(f).
	ponents: benem: egradability lity in water ccumulative potential ponents: benem: ion coefficient: n- hol/water ility in soil ata available	benem: agradability : lity in water : ccumulative potential ponents: benem: ion coefficient: n- ion coefficient: n- ion/water ility in soil ata available utt: ssment :	ponents: benem: begradability : Result: Not read Biodegradation Exposure time: Method: OECD lity in water : Degradation hat ccumulative potential ponents: ponents: : log Pow: -2.22 biologradation hat : ion coefficient: n- ion coefficient: n- : log Pow: -2.22 bility in soil : : ata available : Its of PBT and vPvB assessment uct: : : ssment : This substance/ to be either personer very persistent 0.1% or higher. er adverse effects : : uct: : : crine disrupting poten- : This substance/ ered to have en

SECTION 13: Disposal considerations

13.1 Waste treatment methods	
Product	 Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
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.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Ertapenem Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	9371366-00008	Date of first issue: 27.08.2021

SECTION 14: Transport information

14.1 UN number : UN 3077 ADR : UN 3077 RID : UN 3077 IMDG : UN 3077 IATA : UN 3077	
ADR : UN 3077 RID : UN 3077 IMDG : UN 3077	
RID : UN 3077 IMDG : UN 3077	
IMDG : UN 3077	
IATA : UN 3077	
14.2 UN proper shipping name	
ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOL N.O.S. (Ertapenem)	ID.
ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOL N.O.S. (Ertapenem)	,
RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOL N.O.S. (Ertapenem)	.ID,
IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOL N.O.S. (Ertapenem)	.ID,
IATA : Environmentally hazardous substance, solid, n.o.s. (Ertapenem)	
14.3 Transport hazard class(es)	
Class Subsidiary risks	
ADN : 9	
ADR : 9	
RID : 9	
IMDG : 9	
IATA : 9	
14.4 Packing group	
ADNPacking group:IIIClassification Code:M7Hazard Identification Number:90Labels:9ADRPacking group:IIIClassification Code:M7Hazard Identification Number:90	





Ertapenem Formulation

SDS Number: 9371366-00008	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021
: 9 : (-)	
: III : M7 r : 90 : 9	
: III : 9 : F-A, S-F	
: 956 : Y956 : III	
: 956 : Y956 : III : Miscellaneous	
: yes	
	9371366-00008 : 9 : (-) : III : M7 90 9 : 99 : III 9 : F-A, S-F : 956 : Y956 : III : Miscellaneous : 956 : Y956 : III : Miscellaneous : 956 : yes : yes : yes : yes : yes : yes : yes : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.



Ertapenem Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	9371366-00008	Date of first issue: 27.08.2021

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (A	nnex 17)	:	Not applicable	
UK REACH Candidate list of sub concern (SVHC) for Authorisatio	, .	:	Not applicable	
The Persistent Organic Pollutant		:	Not applicable	
Regulation (EU) 2019/1021 as a ain)	mended for Great Brit-			
Regulation (EC) on substances t	that deplete the ozone	:	Not applicable	
layer UK REACH List of substances s	ubject to authorisation	:	Not applicable	
(Annex XIV)				
GB Export and import of hazardo Informed Consent (PIC) Regulat		:	Not applicable	
Control of Major Accident Hazard		MA	.H)	
-	-		Quantity 1	Quantity 2
E1	ENVIRONMENTAL		100 t	200 t

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

HAZARDS

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
Full text of H-Statements		
H334	:	May cause allergy or asthma symptoms or breathing difficul- ties if inhaled.
H400	:	Very toxic to aquatic life.
H411	:	Toxic to aquatic life with long lasting effects.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Ertapenem Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	9371366-00008	Date of first issue: 27.08.2021

Full text of other abbreviations

Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Resp. Sens.	:	Respiratory sensitisation
GB EH40	:	UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA	:	Long-term exposure limit (8-hour TWA reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road: AIIC - Australian Inventory of Industrial Chemicals: ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; 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 carrving 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

Further information

Classification of the mixture:	Classification procedure:
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/

Classification of the m	ixture:	Classification procedure
Resp. Sens. 1	H334	Calculation method
Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 2	H411	Calculation method



Ertapenem Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	9371366-00008	Date of first issue: 27.08.2021

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.

GB / EN