Commission Regulation (EU) 2020/878



### Ertapenem Formulation

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#### **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 Innishannon County Cork - Ireland
	Telephone	:	353 214329300
	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)

Respiratory sensitisation,	Category 1
----------------------------	------------

Short-term (acute) aquatic hazard, Category 1

gory 1 Long-term (chronic) aquatic hazard, Cat- H<sup>2</sup> egory 2

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. H400: Very toxic to aquatic life.

H411: Toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

#### Labelling (REGULATION (EC) No 1272/2008)

•

Hazard pictograms



Signal word

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according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Hazar	d statements	:	difficulties if inhale	e allergy or asthma symptoms or breathing ed. to aquatic life with long lasting effects.
Preca	utionary statements	:		athing dust. ase to the environment. viratory protection.
			keep comfortable	experiencing respiratory symptoms: Call a

#### 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.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 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	>= 70 - < 90



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			M-Factor (Acute aquatic toxicity): 1		
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 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 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).

# 4.3 Indication of any immediate medical attention and special treatment needed

the skin.

The star suit		The standard mathematically and summarity sha
Treatment	:	Treat symptomatically and supportively.

Contact with dust can cause mechanical irritation or drying of

Dust contact with the eyes can lead to mechanical irritation.



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#### **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 3	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	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).
<b>6.2 Environmental precautions</b> Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

#### 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 Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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		Soak up with ine Avoid dispersal with compressed Dust deposits sh 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). nould not be allowed to accumulate on surfac- y form an explosive mixture if they are re- atmosphere in sufficient concentration. ning materials from spill with suitable absor- al regulations may apply to releases and dis- terial, as well as those materials and items cleanup of releases. You will need to deter- ulations are applicable. I 15 of this SDS provide information regarding national 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	:	Avoid breathing 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.



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areas and containers			Store in accorda	nce with the particular national regulations.	
Advice on common storage		:	Do not store with the following product types: Strong oxidizing agents		
7.3 Specific end use(s) Specific use(s)		:	No data available	9	

#### **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

#### Occupational Exposure Limits

dusts non-specific

4 mg/m3 Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust) Basis: IE OEL

10 mg/m3 Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable dust) Basis: IE OEL

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 I.S. 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

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	and body protection iratory protection	applications chemicals of glove manu end of work Skin should If adequate sure assess ommended	for the product. Change gloves often! For special s, we recommend clarifying the resistance to of the aforementioned protective gloves with the facturer. Wash hands before breaks and at the day. be washed after contact. local exhaust ventilation is not available or expo- sment demonstrates exposures outside the rec- guidelines, use respiratory protection. should conform to I.S. EN 143
Filter type		: Particulates	type (P)

### **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Physical state	:	powder
Colour	:	white
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
рН	:	No data available
Viscosity Viscosity, dynamic	:	No data available

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Viscosity, kinematic		:	No data available	e	
:	Solubili Wat	ty(ies) er solubility	:	No data available	e
	Partition octanol	n coefficient: n- /water	:	No data available	e
,	Vapour	pressure	:	No data available	e
ļ	Relative	e density	:	No data available	e
I	Density		:	No data available	e
I	Relative vapour density		:	No data available	e
l		characteristics icle size	:	No data available	e
		formation			
	Explosi	ves	:	Not explosive	
(	Oxidizir	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Evapor	ation rate	:	No data available	e
I	Molecu	lar weight	:	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 reacti	ons
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

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#### **10.6 Hazardous decomposition products**

No hazardous decomposition products are known.

#### **SECTION 11: Toxicological information**

#### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

#### 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 Application Route: Intravenous

#### 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.

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Com	oonents:		
Ertap	enem:		
Expos	sure routes ssment	: inhalation (dus : Probability of r animal testing	t/mist/fume) espiratory sensitisation in humans based o
Resul	lt	: positive	
	a <b>cell mutagenicity</b> lassified based on ava	ailable information.	
Com	oonents:		
Ertap	enem:		
-	toxicity in vitro	: Test Type: Bao Result: negativ	cterial reverse mutation assay (AMES) /e
		Test Type: Alk Test system: ra Result: negativ	
			romosomal aberration Chinese hamster ovary cells /e
			vitro mammalian cell gene mutation test uman lymphoblastoid cells ve
Geno	toxicity in vivo	: Test Type: Mic Species: Mous Result: negativ	e
Carci	nogenicity		
Not cl	assified based on ava	ailable information.	
Repro	oductive toxicity		
Not cl	assified based on ava	ailable information.	
<u>Com</u>	oonents:		
Ertap	enem:		
Effect	s on fertility	Species: Rat Application Ro Fertility: NOAE	tility/early embryonic development ute: Intravenous L: 700 mg/kg body weight ects on fertility and early embryonic develo ected.
		Test Type: Fer Species: Mous Fertility: NOAE Result: No effe	e L: 700
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Effec ment	ts on foetal develop-	Species: M Application Developme	Development ouse Route: Intravenous injection ntal Toxicity: NOAEL: 700 mg/kg body weight effects on early embryonic development
		Species: M Application Developme Symptoms:	Route: Intravenous injection ntal Toxicity: NOAEL: 350 mg/kg body weight Reduced body weight The mechanism or mode of action may not be rele-
	<b>F - single exposure</b> lassified based on ava	ilable information.	
	<b>F - repeated exposure</b> lassified based on ava		
Repe	ated dose toxicity		
Com	ponents:		
Ertar	benem:		
Spec LOAE Appli Expo	ies EL cation Route sure time et Organs	: Rat : 2 mg/kg : Intravenous : 2 Weeks : Blood : The mecha mans.	s nism or mode of action may not be relevant in hu-
Expo	EL cation Route sure time et Organs	: Rat : 60 mg/kg : Intravenous : 6 Months : Blood : The mecha mans.	s nism or mode of action may not be relevant in hu-
Spec NOAI LOAE Appli	EL	: Monkey : 360 mg/kg : 500 mg/kg	s

Application Route:IntravenousExposure time:27 WeeksTarget Organs:Liver, KidneyRemarks:The mechanism or mode of action may not be relevant in humans.

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#### Aspiration toxicity

Not classified based on available information.

#### 11.2 Information on other hazards

#### Endocrine disrupting properties

#### Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

#### Experience with human exposure

#### **Components:**

#### Ertapenem:

Inhalation Ingestion	<ul><li>Remarks: May cause sensitisation by inhalation.</li><li>Symptoms: Diarrhoea, Nausea, Headache, vaginitis</li></ul>
-------------------------	--

#### **SECTION 12: Ecological information**

#### 12.1 Toxicity

#### **Components:**

#### Ertapenem:

Enapenem.		
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



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	M-Fact icity)	or (Acute aquatic tox-	:	1	
	Toxicity	/ to microorganisms	:	EC10 : 3.9 mg/l Exposure time: 3 Test Type: Respir	
Toxicity to fish (Chronic tox- icity)		:	NOEC: 2.5 mg/l Exposure time: 32 Species: Pimepha Method: OECD Te	ales promelas (fathead minnow)	
		/ to daphnia and other invertebrates (Chron- ity)	:	Exposure time: 21	magna (Water flea)

#### 12.2 Persistence and degradability

#### Components:

_		
Erta	penem	ו:

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 4.7 % Exposure time: 28 d Method: OECD Test Guideline 301B
Stability in water	:	Degradation half life (DT50): 15.3 d

#### 12.3 Bioaccumulative potential

**Components:** 

Erta	penem:

Partition coefficient: n-	:	log Pow: -2.22
octanol/water		

#### 12.4 Mobility in soil

No data available

#### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment

: 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.

#### **12.6 Endocrine disrupting properties**

Product:

```
Assessment
```

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to



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			e 57(f) or Commission Delegated regulation 00 or Commission Regulation (EU) 2018/605 at or higher.
	r adverse effects ata available		
SECTION	13: Disposal con	siderations	
	13: Disposal consistent of the second s		
	e treatment methods	s : Dispose of in According to t are not produc Waste codes discussion wit	accordance with local regulations. he European Waste Catalogue, Waste Codes ct specific, but application specific. should be assigned by the user, preferably in h the waste disposal authorities. e of waste into sewer.

14.1 UN number or ID number		
ADN	:	UN 3077
ADR	:	UN 3077
RID	:	UN 3077
IMDG	:	UN 3077
ΙΑΤΑ	:	UN 3077
14.2 UN proper shipping name		
ADN	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ertapenem)
ADR	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ertapenem)
RID	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ertapenem)
IMDG	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ertapenem)
ΙΑΤΑ	:	Environmentally hazardous substance, solid, n.o.s. (Ertapenem)

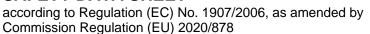
#### 14.3 Transport hazard class(es)

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				Class	Subsidiary risks
Δ			:	9	
	ADR		:	9	
	RID		:	9	
	MDG		÷	9	
	ATA		÷	9	
			•	9	
		ig group			
P C H	Classifi	g group cation Code Identification Number	:	III M7 90 9	
P C H L	Classifi Iazard .abels	g group cation Code Identification Number restriction code	:	III M7 90 9 (-)	
P C H	Classifi	g group cation Code Identification Number	:	III M7 90 9	
P L	MDG Packing abels mS C	g group ode	:	III 9 F-A, S-F	
P a P P	Packing aircraft Packing		:	956 Y956 III Miscellaneous	
l/ P	ATA (I	Passenger) g instruction (passen-	:	956	
P P	Packing	g instruction (LQ) g group	:	Y956 III Miscellaneous	
14.5 E	Enviro	nmental hazards			
	<b>ADN</b> Enviror	nmentally hazardous	:	yes	
	<b>ADR</b> Enviror	nmentally hazardous	:	yes	





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#### RID

Environmentally hazardous	:	yes	
IMDG Marine pollutant	:	yes	
IATA (Passenger) Environmentally hazardous	:	yes	
IATA (Cargo)			

Environmentally hazardous : 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 Maritime transport in bulk according to IMO instruments

Remarks

: Not applicable for product as supplied.

### **SECTION 15: Regulatory information**

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	:	Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
Regulation (EC) No 1005/2009 on substances that de- plete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)	:	Not applicable
Regulation (EC) No 649/2012 of the European Parlia- ment and the Council concerning the export and import	:	Not applicable
of dangerous chemicals REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Sovero III: Directive 2012/18/ELL of the European Parlian	nont	and of the Council

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

		Quantity 1	Quantity 2
E1	ENVIRONMENTAL	100 t	200 t
	HAZARDS		

#### Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS : not determined



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C	DSL		:	not determined	
I	ECSC		:	not determined	
		cal safety assessmer Safety Assessment ha		ot been carried out	
SEC	TION	16: Other information	on		
C	Other i	nformation	:		ges have been made to the previous version the body of this document by two vertical
F	Full tex	xt of H-Statements			
ŀ	1334		:	May cause allergy ties if inhaled.	y or asthma symptoms or breathing difficul-
-	H400 :		:	Very toxic to aqua	
F	4411		:	Toxic to aquatic li	fe with long lasting effects.
F	Full tex	xt of other abbreviation	ons		
A F			:		ic) aquatic hazard
I	E OEL	. / OELV - 8 hrs (TWA)	:		osure limit value (8-hour 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 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; 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 - (Quanti-



### Ertapenem Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.03.2023
5.1	26.09.2023	20976-00022	Date of first issue: 03.11.2014

tative) 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

#### Further information

Sources of key data used to compile the Safety Data	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-
Sheet		cy, http://echa.europa.eu/

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

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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