

according to the Hazardous Products Regulations

Ertapenem Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/26/2023
6.2	09/28/2024	20963-00023	Date of first issue: 11/03/2014

SECTION 1. IDENTIFICATION

Product name	:	Ertapenem Formulation
Other means of identification	:	No data available

Manufacturer or supplier's details

Company name of supplier	:	Merck & Co., Inc
Address	:	126 E. Lincoln Avenue
		Rahway, New Jersey U.S.A. 07065
Telephone	:	908-740-4000
Emergency telephone	:	1-908-423-6000
E-mail address	:	EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use	: Pharmaceu	tical
Restrictions on use	: Not applica	ble

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulation	S
---	---

Respiratory sensitization	:	Category 1

GHS label elements

Hazard Statements

Hazard pictograms



Signal Word	:	Danger
-------------	---	--------

: H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary Statements

Prevention:

P261 Avoid breathing dust. 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 doctor.

Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

according to the Hazardous Products Regulations



Ertapenem Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/26/2023
6.2	09/28/2024	20963-00023	Date of first issue: 11/03/2014

Other hazards

Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Ertapenem	No data availa- ble	153773-82-1	>= 80 - <= 100 *

* Actual concentration or concentration range is withheld as a trade secret

SECTION 4. 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.
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 delayed	:	May cause allergy or asthma symptoms or breathing difficulties 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.
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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray



according to the Hazardous Products Regulations

Ertapenem Formulation

Vers 6.2	sion	Revision Date: 09/28/2024		0S Number: 963-00023	Date of last issue: 09/26/2023 Date of first issue: 11/03/2014
				Alcohol-resistant Carbon dioxide (C Dry chemical	
	Unsuita media	able extinguishing	:	None known.	
	Specifi fighting	c hazards during fire I	:	concentrations, and potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. bustion products may be a hazard to health.
	Hazard ucts	lous combustion prod-	:	Carbon oxides Metal oxides	
	Specifi ods	c extinguishing meth-	:	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
		l protective equipment fighters	:		e, wear self-contained breathing apparatus. rective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
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.
Methods and materials for containment and cleaning up	:	Surround spill with absorbents and place a damp covering over the area to minimize entry of the material into the air. Add excess liquid to allow the material to enter into solution. Soak up with inert absorbent material. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.



according to the Hazardous Products Regulations

Ertapenem Formulation

Version 6.2	Revision Date: 09/28/2024	SDS Numbe 20963-00023			
			13 and 15 of this SDS provide information regarding cal or national requirements.		
SECTION	7. HANDLING AND ST	TORAGE			
Tech	nical measures	causing a Provide a	ctricity may accumulate and ignite suspended dust in explosion. dequate precautions, such as electrical grounding ing, or inert atmospheres.		
	I/Total ventilation ce on safe handling	 Use only Do not br Do not sy Avoid con Avoid pro Handle ir practice, assessm Keep cor Already s to asthma should cor respirator Minimize Keep cor Keep awa Take pre Take care 	with adequate ventilation. eathe dust. vallow. htact with eyes. longed or repeated contact with skin. accordance with good industrial hygiene and safety based on the results of the workplace exposure ent tainer tightly closed. ensitized individuals, and those susceptible a, allergies, chronic or recurrent respiratory disease, nsult their physician regarding working with y irritants or sensitizers. dust generation and accumulation. tainer closed when not in use. ay from heat and sources of ignition. cautionary measures against static discharges. e to prevent spills, waste and minimize release to the		
	litions for safe storage	Keep tigh Store in a	ent. roperly labeled containers. tly closed. ccordance with the particular national regulations. pre with the following product types:		
mato			Strong oxidizing agents		

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Ertapenem	153773-82-1	TWA	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 designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
----------------------	---	---





according to the Hazardous Products Regulations

Ertapenem Formulation

Version 6.2	Revision Date: 09/28/2024	SDS Number: 20963-00023	Date of last issue: 09/26/2023 Date of first issue: 11/03/2014
Pe	rsonal protective equipn	nent	
Re	spiratory protection	exposure asse	al exhaust ventilation is not available or ssment demonstrates exposures outside the guidelines, use respiratory protection.
На	Filter type nd protection	: Particulates typ	be
	Material	: Chemical-resis	tant gloves
	Remarks	on the concent time is not dete For special app resistance to cl gloves with the	to protect hands against chemicals depending ration specific to place of work. Breakthrough ermined for the product. Change gloves often! plications, we recommend clarifying the hemicals of the aforementioned protective glove manufacturer. Wash hands before he end of workday.
Ey	e protection		ving personal protective equipment:
	in and body protection giene measures	: If exposure to of eye flushing sy working place. When using do	washed after contact. chemical is likely during typical use, provide stems and safety showers close to the not eat, drink or smoke. nated clothing before re-use.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	white
Odor	:	No data available
Odor 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, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available



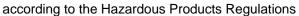


Ertapenem Formulation

Vers 6.2	sion	Revision Date: 09/28/2024		S Number: 63-00023	Date of last issue: 09/26/2023 Date of first issue: 11/03/2014
		explosion limit / Lower bility limit	:	No data available	
	Vapor p	pressure	:	No data available	•
	Relative	e vapor density	:	No data available	,
	Relative	e density	:	No data available	•
	Density		:	No data available	•
	Solubili Wate	ty(ies) er solubility	:	No data available	
	Partition octanol	n coefficient: n-	:	No data available	
		ition temperature	:	No data available	
	Decom	position temperature	:	No data available	
	Viscosit Visc	ty osity, dynamic	:	No data available	
	Visc	osity, kinematic	:	No data available	
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance or	mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	
	Particle Particle	characteristics size	:	No data available	

SECTION 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, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.





Ertapenem Formulation

Version	Revision Date: 09/28/2024	SDS Number:	Date of last issue: 09/26/2023
6.2		20963-00023	Date of first issue: 11/03/2014

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation 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 sensitization

Skin sensitization

Not classified based on available information.

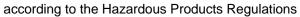
Respiratory sensitization

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

Components:

Ertapenem:

Routes of exposure	:	inhalation (dust/mist/fume)
Assessment	:	Probability of respiratory sensitization in humans based on





Ertapenem Formulation

ersion 2	Revision Date: 09/28/2024	-	0S Number: 963-00023	Date of last issue: 09/26/2023 Date of first issue: 11/03/2014
Resul	t	:	animal testing positive	
	assified based on ava	ailable	information.	
Comp	oonents:			
Ertap	enem:			
Genot	toxicity in vitro	:	Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)
			Test Type: Alkalir Test system: rat h Result: negative	
				nosomal aberration nese hamster ovary cells
				o mammalian cell gene mutation test nan lymphoblastoid cells
Genot	toxicity in vivo	:	Test Type: Micror Species: Mouse Result: negative	nucleus test
	nogenicity			
	assified based on ava	ailable	information.	
-	oductive toxicity assified based on ava	ailahle	information	
	oonents:			
	enem:			
-	s on fertility	:	Species: Rat Application Route Fertility: NOAEL:	700 mg/kg body weight son fertility and early embryonic
			Test Type: Fertilit Species: Mouse Fertility: NOAEL: Result: No effects	700
Effect	s on fetal developmer	nt :	Developmental To	opment e: Intravenous injection oxicity: NOAEL: 700 mg/kg body weigh s on early embryonic development.

according to the Hazardous Products Regulations



Ertapenem Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/26/2023
6.2	09/28/2024	20963-00023	Date of first issue: 11/03/2014

Test Type: Development Species: Mouse Application Route: Intravenous injection Developmental Toxicity: NOAEL: 350 mg/kg body weight Symptoms: Reduced body weight Remarks: The mechanism or mode of action may not be relevant in humans.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

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

Aspiration toxicity

Not classified based on available information.

:

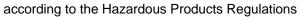
Experience with human exposure

Components:

Ertapenem:

Inhalation

Remarks: May cause sensitization by inhalation.





Ertapenem Formulation

Version 6.2	Revision Date: 09/28/2024		963-00023	Date of last issue: 09/26/2023 Date of first issue: 11/03/2014
Inge	stion	:	Symptoms: Diarrh	ea, Nausea, Headache, vaginitis
SECTION	N 12. ECOLOGICAL INFO	DRN	ATION	
Ecot	toxicity			
Com	ponents:			
Erta	penem:			
Toxi	city to fish	:	LC50 (Pimephales Exposure time: 96	s promelas (fathead minnow)): > 1,000 mg/l s h
	city to daphnia and other atic invertebrates	:	EC50 (Daphnia m Exposure time: 48	agna (Water flea)): > 500 mg/l s h
Toxi plant	city to algae/aquatic ts	:	mg/l Exposure time: 72	
			Method: OECD To	est Guideline 201
			NOEC (Pseudokir mg/l	chneriella subcapitata (green algae)): 51
			Exposure time: 72 Method: OECD Te	
			EC50 (Anabaena Exposure time: 72 Method: OECD Te	
			NOEC (Anabaena Exposure time: 72 Method: OECD To	
Toxi icity)	city to fish (Chronic tox-	:	NOEC (Pimephale Exposure time: 32 Method: OECD Te	
aqua	city to daphnia and other atic invertebrates (Chron- xicity)	:	NOEC (Daphnia r Exposure time: 21 Method: OECD Te	
Toxi	city to microorganisms	:	EC10: 3.9 mg/l Exposure time: 3 Test Type: Respir	
Pers	sistence and degradabili	ty		
<u>Com</u>	ponents:			
	penem:			
Biod	egradability	:	Result: Not readily Biodegradation: 4 Exposure time: 28	l.7 %



according to the Hazardous Products Regulations

Ertapenem Formulation

Version 6.2	Revision Date: 09/28/2024	SDS Number: 20963-00023	Date of last issue: 09/26/2023 Date of first issue: 11/03/2014	
		Method: OE0	CD Test Guideline 301B	
Stab	ility in water	: Degradation	half life (DT50): 15.3 d	
Bioa	ccumulative potential			
Com	ponents:			
Parti	penem: tion coefficient: n- nol/water	: log Pow: -2.2	22	
	ility in soil lata available			
	er adverse effects lata available			

SECTION 13. DISPOSAL CONSIDERATIONS

Waste from residues	:	Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 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	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passen- ger aircraft)	:	956
Environmentally hazardous	:	yes



according to the Hazardous Products Regulations

Ertapenem Formulation

Version 6.2	Revision Date: 09/28/2024	SDS Number: 20963-00023	Date of last issue: 09/26/2023 Date of first issue: 11/03/2014
UN	DG-Code number oper shipping name	: UN 3077 : ENVIRONN N.O.S. (Ertapenerr	IENTALLY HAZARDOUS SUBSTANCE, SOLID,
Cla	ISS	: 9	
Pa	cking group	: 111	
Lab	pels	: 9	
Em	S Code	: F-A, S-F	
Ma	rine pollutant	: yes	

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

Not applicable for product as supplied.

Domestic regulation

TDG		
UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ertapenem)
Class	:	9
Packing group	:	III
Labels	:	9
ERG Code	:	171
Marine pollutant	:	yes(Ertapenem)

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.

SECTION 15. REGULATORY INFORMATION

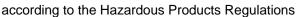
The ingredients of this product are	report	ed ir	n the	following	inventories:
	-				

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

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule;





Ertapenem Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/26/2023
6.2	09/28/2024	20963-00023	Date of first issue: 11/03/2014

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

Sources of key data used to compile the Material Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/
Revision Date Date format	:	09/28/2024 mm/dd/yyyy

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.

CA / Z8