

according to the Hazardous Products Regulations

Tedizolid Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
5.1	09/30/2023	657039-00019	Date of first issue: 05/02/2016

SECTION 1. IDENTIFICATION

Product name	:	Tedizolid Injection Formulation
Other means of identification	:	No data available

Manufacturer or supplier's details

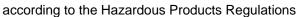
Company name of supplier	:	Merck & Co., Inc
Address	:	126 E. Lincoln Avenue
		Rahway, New Jersey U.S.A. 07065
Telephone	:	908-740-4000
Emergency telephone	:	1-908-423-6000
E-mail address	:	EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use	: Pharmaceutical
Restrictions on use	: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accord Reproductive toxicity	an :	ce with the Hazardous Products Regulations Category 2
Specific target organ toxicity - repeated exposure	:	Category 2 (Bone marrow, Blood, Gastrointestinal tract)
GHS label elements		
Hazard pictograms	:	
Signal Word	:	Warning
Hazard Statements	:	H361d Suspected of damaging the unborn child. H373 May cause damage to organs (Bone marrow, Blood, Gas- trointestinal tract) through prolonged or repeated exposure.
Precautionary Statements	:	 Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe dust. P280 Wear protective gloves, protective clothing, eye protection and face protection. Response: P308 + P313 IF exposed or concerned: Get medical attention. Storage:
		P405 Store locked up.





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Disposal:

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

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

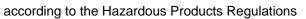
Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Tedizolid Phosphate	No data availa- ble	856867-55-5	67

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.
If inhaled	:	If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	:	
In case of eye contact	:	
If swallowed	:	
Most important symptoms and effects, both acute and delayed	:	Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure. Contact with dust can cause mechanical irritation or drying of the skin.
Protection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. 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





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Suitable extinguishing media		:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical		
	Unsuitat media	ble extinguishing	:	None known.	
	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	
	Hazardo ucts	us combustion prod-	:	Carbon oxides	
	Specific ods	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
	Special p for fire-fi	protective equipment ghters	:	In the event of fire Use personal prot	e, wear self-contained breathing apparatus. ective 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	:	Sweep up or vacuum up spillage and collect in suitable container for disposal. 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. 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. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures

: Static electricity may accumulate and ignite suspended dust causing an explosion.

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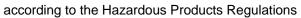
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Local/Total ventilation Advice on safe handling		and bonding, Use only with Do not breath Do not swallo Avoid contact Avoid prolong Handle in acc practice, base assessment Minimize dus Keep contain Keep away fr Take precaut	W.
Condit	tions for safe storage	: Keep in prope Store locked	•
Materi	als to avoid		rdance with the particular national regulations. with the following product types: ng agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

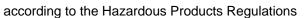
Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis			
Tedizolid Phosphate	856867-55-5	TWA	400 μg/m3 (OEB 2)	Internal			
Engineering measures	compound. All engineerin design and op	Use feasible engineering controls to minimize exposure to compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.					
Personal protective equipment							
Respiratory protection Filter type	 If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Particulates type 						
Hand protection Material	: Chemical-res	Chemical-resistant gloves					
Eye protection	If the work en mists or aeros Wear a faces	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.					
Skin and body protection	: Work uniform	or laboratory co	Work uniform or laboratory coat.				





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	Hygien	e measures	:	eye flushing syste working place. When using do no Wash contaminate The effective oper engineering contra appropriate degov	emical is likely during typical use, provide ems and safety showers close to the ot eat, drink or smoke. ed clothing before re-use. ration of a facility should include review of ols, proper personal protective equipment, whing and decontamination procedures, monitoring, medical surveillance and the tive controls.
SEC	CTION 9	. PHYSICAL AND CHI	EMIC	CAL PROPERTIES	6
	Appear	ance	:	(lyophilized)	
	Color		:	white to off-white	
	Odor		:	odorless	
	Odor T	hreshold	:	No data available	9
	рН		:	7.4 - 8.1	
	Melting	point/freezing point	:	No data available	9
	Initial b range	oiling point and boiling	:	No data available	9
	Flash p	oint	:	Not applicable	
	Evapor	ation rate	:	Not applicable	
	Flamma	ability (solid, gas)	:	May form explosi handling or other	ive dust-air mixture during processing, means.
	Flamma	ability (liquids)	:	Not applicable	
		explosion limit / Upper bility limit	:	No data available	9
		explosion limit / Lower bility limit	:	No data available	•
	Vapor p	pressure	:	Not applicable	
	Relative	e vapor density	:	Not applicable	
	Relative	e density	:	No data available	9
	Density	,	:	No data available	9
	Solubili Wat	ty(ies) er solubility	:	No data available	9





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	Partition coefficient: n- octanol/water Autoignition temperature Decomposition temperature		::	Not applicable No data available No data available	
		ity cosity, kinematic ive properties	:	No data available Not explosive	9
		ng properties ular weight e size	: : :	The substance o No data available 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 Hazardous decomposition products	:	Oxidizing agents No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

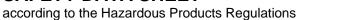
- Information on likely routes of exposure
- Inhalation Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Tedizolid Phosphate:		
Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg
		LD50 (Mouse): > 2,000 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Mouse): 256 - 274 mg/kg Application Route: Intravenous





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LD50 (Rat): 244 mg/kg Application Route: Intravenous

LD50 (Dog): 200 mg/kg Application Route: Intravenous

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:

Tedizolid Phosphate:

Genotoxicity in vitro :	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: Chromosome aberration test in vitro Result: positive
Genotoxicity in vivo :	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Result: negative
	Test Type: unscheduled DNA synthesis assay Species: Rat Result: negative
Germ cell mutagenicity - : Assessment	Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity

Not classified based on available information.

:

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

Tedizolid Phosphate:

Effects on fertility

Test Type: Fertility/early embryonic development

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				Species: Rat, fem Application Route Fertility: NOAEL: Result: No effects Test Type: Fertilit Species: Rat, mal Application Route	: Oral 15 mg/kg body weight on fertility. y e
				Fertility: NOAEL: Result: No effects	50 mg/kg body weight on fertility.
I	Effects on fetal development		:	Species: Mouse Application Route Developmental To	o-fetal development : Oral oxicity: LOAEL: 25 mg/kg body weight fetal weight., Skeletal malformations.
				Species: Rat Application Route Developmental To	o-fetal development : Oral oxicity: LOAEL: 15 mg/kg body weight fetal weight., Skeletal malformations.
				Species: Rat Application Route Developmental To	o-fetal development : Oral oxicity: NOAEL: 2.5 mg/kg body weight fetal weight., Skeletal malformations.
	Reprod sessme	luctive toxicity - As- ent	:	Some evidence o animal experimen	f adverse effects on development, based on ts.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

May cause damage to organs (Bone marrow, Blood, Gastrointestinal tract) through prolonged or repeated exposure.

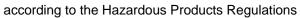
Components:

Tedizolid Phosphate:		
Target Organs Assessment	:	Bone marrow, Blood, Gastrointestinal tract May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Species	: Rat, female
NOAEL	: 10 mg/kg
Application Route	: Oral





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ersion 1	Revision Date: 09/30/2023		OS Number: 7039-00019	Date of last issue: 04/04/2023 Date of first issue: 05/02/2016
	sure time et Organs	:	28 d Lymph nodes,	thymus gland, Bone marrow
Expos		:	Rat, male 30 mg/kg Oral 28 d Bone marrow,	spleen, Lymph nodes, thymus gland
Expos		:	Rat, female 15 mg/kg Intravenous 28 d Gastrointestina	al tract
Expos		:	Rat, male 30 mg/kg Intravenous 28 d Gastrointestina	al tract
	EL	:	Rat 2 mg/kg 5 mg/kg Oral 6 Months	
	EL cation Route sure time	:	Dog 400 mg/kg Oral 28 d Vomiting	
•	ation toxicity assified based on ava	ailable	information.	
Expe	rience with human e	xposı	ire	
Com	oonents:			
Tediz Inhala Inges		:		usea, Headache, Diarrhea, Vomiting, Dizziness usea, Headache, Diarrhea, Vomiting, Dizziness
ECTION	12. ECOLOGICAL IN	IFOR	MATION	
Ecoto	oxicity			
<u>Com</u>	oonents:			

Tedizolid Phosphate:

Toxicity to algae/aquatic	:	EC50 (Anabaena flos-aquae): 0.313 mg/l
plants		Exposure time: 72 h
		Method: OECD Test Guideline 201



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			Exposure time:	ena flos-aquae): 0.0632 mg/l 72 h Test Guideline 201	
Toxic icity)	Toxicity to fish (Chronic tox- icity)		mg/l Exposure time:	ales promelas (fathead minnow)): 0.03175 32 d Test Guideline 210	
aquat	ity to daphnia and other tic invertebrates (Chron-	:	NOEC (Daphnia magna (Water flea)): 0.6 mg/l Exposure time: 21 d		
	ic toxicity) Toxicity to microorganisms				
Persi	stence and degradabil	ity			
Com	ponents:				
	colid Phosphate: egradability	:	Biodegradation Exposure time:		
Stabi	lity in water	:	Hydrolysis: 0 %	o(5 d)	
Bioa	ccumulative potential				
<u>Com</u>	ponents:				
Partit	colid Phosphate: ion coefficient: n- ol/water	:	log Pow: 1.3		
Mobi	lity in soil				
Com	ponents:				
Distri	colid Phosphate: bution among environ- al compartments	:	log Koc: 2.6		
	r adverse effects ata available				



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SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods		
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. (Tedizolid Phosphate)
Class		9
Packing group		u III
Labels		9
Environmentally hazardous	:	yes
IATA-DGR		
UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Tedizolid Phosphate)
Class	:	9
Packing group	:	III
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. (Tedizolid Phosphate)
Class		9
Packing group	:	u III
Labels	÷	9
EmS Code	:	Ğ F-A, S-F
Marine pollutant	÷	ves
	•	

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

Not applicable for product as supplied.

Domestic regulation

TDG

LIN number		
UN number	•	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
1 11 0		



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Labels ERG 0 Marine	-	:	N.O.S. (Tedizolid Phosp 9 III 9 171 yes(Tedizolid Ph	,

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 reported in	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; 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,



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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	:	09/30/2023 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.

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