

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

Ertugliflozin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	2338808-00018	Date of first issue: 13.12.2017

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

1.1	Product identifier Trade name	:	Ertugliflozin Formulation						
1.2	1.2 Relevant identified uses of the substance 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 Piercetown A86 HD21 Dunboyne, Ireland						
	Telephone	:	908-740-4000						
	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

2.1 Classification of the substance or mixture									
Classification (REGULATIO	Classification (REGULATION (EC) No 1272/2008)								
Serious eye damage, Categ	ory	1	H318: Causes serious eye damage.						
2.2 Label elements									
Labelling (REGULATION (Labelling (REGULATION (EC) No 1272/2008)								
Hazard pictograms	Hazard pictograms :								
Signal word	:	Danger							
Hazard statements	:	H318	Causes serious eye damage.						
Precautionary statements	:	Prevention	1:						

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		P280 Wea	ar eye protection/ face protection.
		Response:	
		with lens	338 + P310 IF IN EYES: Rinse cautiously water for several minutes. Remove contact es, if present and easy to do. Continue rins- Immediately call a POISON CENTER/ doctor.

Hazardous components which must be listed on the label:

Ertugliflozin

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.

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)
Ertugliflozin	1210344-83-4	Acute Tox. 4; H302 Skin Corr. 1B; H314 Eye Dam. 1; H318 STOT RE 2; H373 (Kidney, Stomach, Prostate)	>= 5 - < 10

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.

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Protect	ion of first-aiders	:	and use the recor	ers should pay attention to self-protection, nmended personal protective equipment Il for exposure exists (see section 8).
lf inhale	ed	:	If inhaled, remove Get medical atter	e to fresh air. tion if symptoms occur.
In case	of skin contact	:	Wash with water Get medical atter	and soap. tion if symptoms occur.
In case	of eye contact	:	for at least 15 mir	ove contact lens, if worn.
If swallo	owed	:	Get medical atter	NOT induce vomiting. tion if symptoms occur. oughly with water.
2 Most im	portant symptoms a	ad c	facts both south	and delayed
Risks	portant symptoms a	:	Causes serious e	-
				can cause mechanical irritation or drying of
1.3 Indication				
Treatm	-	meo		special treatment needed
Treatme	-	meo :		a special treatment needed cally and supportively.
SECTION	ent 5: Firefighting meas	:	Treat symptomati	-
SECTION \$	ent 5: Firefighting meas ishing media	: sur	Treat symptomati	-
SECTION \$	ent 5: Firefighting meas	:	Treat symptomati	cally and supportively.
SECTION 5 5.1 Extingu Suitable	ent 5: Firefighting meas ishing media	: sur	Treat symptomati es Water spray Alcohol-resistant Carbon dioxide (0	cally and supportively.
SECTION Solution	ent 5: Firefighting meas ishing media e extinguishing media uble extinguishing	: sure :	Treat symptomaties	cally and supportively. foam CO2)
5ECTION 5.1 Extingu Suitable Unsuita media 5.2 Special	ent 5: Firefighting meas ishing media e extinguishing media able extinguishing hazards arising from c hazards during fire-	: sure :	Treat symptomati es Water spray Alcohol-resistant Carbon dioxide (C Dry chemical None known. e substance or mi Avoid generating concentrations, a potential dust exp	cally and supportively. foam CO2) xture dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a

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5.3 Advice for firefighters									
	ial protective equipment efighters	:		e, wear self-contained breathing apparatus. tective equipment.					
Spec ods	ific extinguishing meth-	:	cumstances and Use water spray	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do					

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. 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	:	Sweep up or vacuum up spillage and collect in suitable con- tainer 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 surfac- es, as these may form an explosive mixture if they are re- leased into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and dis- posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter- mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
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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

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Local/Total ventilation Advice on safe handling		:::	 2338808-00018 Date of first issue: 13.12.2017 and bonding, or inert atmospheres. Use only with adequate ventilation. Do not breathe dust. Do not get in eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and practice, based on the results of the workplace exposur sessment Keep container tightly closed. 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 environment. 		
Hygiene measures		:	flushing systems place. When usin nated clothing be The effective ope engineering cont appropriate dego	eration of a facility should include review of trols, proper personal protective equipment, owning and decontamination procedures, e monitoring, medical surveillance and the	
7.2 Condi	tions for safe storage,	inc	luding any incom	npatibilities	
Requ	irements for storage and containers	:	Keep in properly	balance of the particular national regulations.	
Advic	Advice on common storage		Do not store with Strong oxidizing	n the following product types: agents	
7.3 Specif	ic end use(s)				
Speci	fic use(s)	:	No data available	e	

. . .

8.1 Control parameters

Occupational Exposure Limit	S
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



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	Cellulo	se	9004-34-6	OELV - 8 hrs (TWA)	10 mg/m3	IE OEL
	Ertuglif	lozin	1210344- 83-4	TWA	10 µg/m3 (OEB 3)	Internal
				Wipe limit	100 µg/100 cm ²	Internal

8.2 Exposure controls

Engineering measures

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Personal protective equipment

Eye/face protection	 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.
Hand protection	
Material	Chemical-resistant gloves
Remarks Skin and body protection	 Consider double gloving. Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Respiratory protection Filter type	 If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143 Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	: powder
Colour	: No data available
Odour	: No data available
Odour Threshold	: No data available

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	Melting	point/freezing point	:	No data available	9	
	Initial b range	oiling point and boiling	:	No data available)	
	Flamma	ability (solid, gas)	:	May form explosi dling or other me	ve dust-air mixture during processing, han- ans.	
	Flamma	ability (liquids)	:	No data available)	
		explosion limit / Upper bility limit	:	: No data available		
		explosion limit / Lower bility limit	:	No data available		
	Flash p	oint	:	Not applicable		
	Auto-ig	nition temperature	:	No data available)	
	Decom	position temperature	:	No data available)	
	рН		:	No data available)	
	Viscosi Visc	ty osity, kinematic	:	Not applicable		
	Solubili Wat	ty(ies) er solubility	:	No data available		
	Partition octanol	n coefficient: n- /water	:	Not applicable		
	Vapour	pressure	:	Not applicable		
	Relative	e density	:	No data available	9	
	Density	,	:	No data available	9	
	Relative	e vapour density	:	Not applicable		
		characteristics icle size	:	No data available)	
		formation				
	Explosi		:	Not explosive		
	Oxidizir	ng properties	:	The substance or	r mixture is not classified as oxidizing.	

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Evaporation rate

: Not applicable

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
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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.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg
		Method: Calculation method

Components:

Ertugliflozin: Acute oral toxicity	:	LD50 (Rat): 500 mg/kg
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Remarks: No data available

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	corrosion/irritation	ilahla infa	was a tila a	
	lassified based on ava	allable inio	mation.	
Asses Metho	Product:Assessment:Method:Result:Components:		skin irritation iDerm t corrosive	
<u>Com</u> r				
-	liflozin:		rraciva	
Resul	IT	: Co	orrosive	
	Serious eye damage/eye irrita Causes serious eye damage.			
	ponents:	, ,		
Ertug	ıliflozin:			
Resul		: Se	vere irritation	
Resp	Respiratory or skin sensitisation			
_	Skin sensitisation Not classified based on availabl		rmation.	
-	Respiratory sensitisation Not classified based on available		rmation.	
Com	Components:			
Ertug	ıliflozin:			
Test T Resul	Туре		cal lymph nod t a skin sensi	le assay (LLNA) tizer.
	cell mutagenicity lassified based on ava	ailable info	rmation	
	ponents:		innation.	
	liflozin:			
-	toxicity in vitro		st Type: Bacto sult: negative	erial reverse mutation assay (AMES)
			st Type: Chro sult: negative	mosome aberration test in vitro
Geno	toxicity in vivo	cyt Sp	st Type: Mam togenetic assa ecies: Rat esult: negative	

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		ogenicity ssified based on availa	able	information.	
	Compo	onents:			
	Ertugli	iflozin:			
		s ation Route ure time	:	Mouse Oral 2 Years negative	
		s ation Route ure time	:	Rat Oral 2 Years negative	
	Carcino ment	ogenicity - Assess-	:	Weight of evidenc cinogen	ce does not support classification as a car-
	Not cla	ductive toxicity ssified based on availa	able	information.	
	Ertugli	iflozin:			
	-	on fertility	:	Species: Rat Application Route Fertility: NOAEL: Remarks: Matern No significant adv	250 mg/kg body weight al toxicity observed. verse effects were reported
				Species: Rabbit Application Route Fertility: NOAEL:	y/early embryonic development :: Oral 200 mg/kg body weight nificant adverse effects were reported
	Effects ment	on foetal develop-	:	Species: Rat Application Route Developmental To	vo-foetal development e: Oral oxicity: NOAEL: 50 mg/kg body weight e developmental effects were observed
				Species: Rabbit Application Route Developmental To	vo-foetal development e: Oral oxicity: NOAEL: 250 mg/kg body weight nificant adverse effects were reported

STOT - single exposure

Not classified based on available information.

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STO	Г - repeated exposure						
Not c	Not classified based on available information. <u>Components:</u>						
<u>Com</u>							
Frtuc	Ertugliflozin:						
Expo Targe	sure routes et Organs ssment	 Oral Kidney, Stoma May cause da exposure. 	ach, Prostate mage to organs through prolonged or repeated				
Repe	ated dose toxicity						
Com	ponents:						
Frtue	gliflozin:						
Spec LOAE Appli	ies	: Rat : 500 mg/kg : Oral : 30 d					
Expo		: Rat : 250 mg/kg : Oral : 30 d : Kidney					
Expo		: Rat : 25 mg/kg : Oral : 180 d : Kidney, Bone,	Stomach				
		: Rat : 25 mg/kg : 90 d : Kidney, Gastro	pintestinal tract, Prostate				
	EL cation Route sure time	: Dog : 150 mg/kg : Oral : 270 d : No significant	adverse effects were reported				
	EL cation Route sure time	: Mouse : 100 mg/kg : Oral : 90 d : No significant	adverse effects were reported				
Spec NOAI Applie		: Mouse : 100 mg/kg : Oral					

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Tar	osure time get Organs narks	: 28 d : Bone : No significa	ant adverse effects were reported
Not	biration toxicity classified based on avai formation on other haza		
Enc	locrine disrupting prop	erties	
	<u>duct:</u> essment	ered to hav REACH Ar (EU) 2017/	nce/mixture does not contain components consid- e endocrine disrupting properties according to ticle 57(f) or Commission Delegated regulation 2100 or Commission Regulation (EU) 2018/605 at 1% or higher.
Exp	perience with human ex	posure	
<u>Cor</u>	nponents:		
	ugliflozin: estion	constipatio	The most common side effects are:, Headache, n, Diarrhoea, Nausea, urinary tract infection, mus- oper respiratory tract infection
SECTIO	DN 12: Ecological info	ormation	

12.1 Toxicity

Components:

Ertugliflozin: Toxicity to algae/aquatic : plants	EC50 (Pseudokirchneriella subcapitata (green algae)): 77 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 50 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to microorganisms :	EC50 : > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 NOEC : 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

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Toxic icity)	city to fish (Chronic tox-	:	Method: OECD T	2 d ales promelas (fathead minnow) Test Guideline 210 icity at the limit of solubility
	city to daphnia and other tic invertebrates (Chron- cicity)		Method: OECD T	
12.2 Pers	istence and degradabil	lity		
<u>Com</u>	ponents:			
	gliflozin: egradability	:	Result: Not readi Biodegradation: Exposure time: 2	40.8 %
12.3 Bioa	ccumulative potential			
<u>Com</u>	ponents:			
Partit	gliflozin: tion coefficient: n- nol/water	:	log Pow: 2.47	
12.4 Mob	ility in soil			
<u>Com</u>	ponents:			
Distri	gliflozin: ibution among environ- al compartments	:	log Koc: 2.88	
12.5 Resu	ults of PBT and vPvB as	sse	ssment	
<mark>Prod</mark> Asse	l <mark>uct:</mark> ssment	:	to be either persi	nixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of
12.6 Endo	ocrine disrupting prope	ertie	es	
<u>Prod</u>	luct:			
Asse	ssment	:	ered to have end REACH Article 5	hixture does not contain components consid- locrine disrupting properties according to 7(f) or Commission Delegated regulation or Commission Regulation (EU) 2018/605 at

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levels of 0.1% or higher.

12.7 Other adverse effects

No data available

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.

SECTION 14: Transport information

14.1 UN number or ID number

	ADN	:	Not regulated as a dangerous good
	ADR	:	Not regulated as a dangerous good
	RID	:	Not regulated as a dangerous good
	IMDG	:	Not regulated as a dangerous good
	ΙΑΤΑ	:	Not regulated as a dangerous good
14.	2 UN proper shipping name		
	ADN	:	Not regulated as a dangerous good
	ADR	:	Not regulated as a dangerous good
	RID	:	Not regulated as a dangerous good
	IMDG	:	Not regulated as a dangerous good
	ΙΑΤΑ	:	Not regulated as a dangerous good
14.	3 Transport hazard class(es)		
	ADN	:	Not regulated as a dangerous good
	ADR	:	Not regulated as a dangerous good
	RID	:	Not regulated as a dangerous good
	IMDG	:	Not regulated as a dangerous good
	ΙΑΤΑ	:	Not regulated as a dangerous good
14.	4 Packing group		
	ADN	:	Not regulated as a dangerous good

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ADR		: Not regulated a	s a dangerous good			
RID		: Not regulated a	s a dangerous good			
IMDG		: Not regulated as a dangerous good				
IATA (Cargo)		: Not regulated a	s a dangerous good			
IATA (Passenger)		: Not regulated a	s a dangerous good			
14.5 Environmental hazards Not regulated as a dangerous good						
14.6 Spe Not a						
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) on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)	:	Not applicable
Regulation (EU) No 649/2012 of the European Parlia- ment and the Council concerning the export and import of dangerous chemicals	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Seveso III: Directive 2012/18/EU of the European Parliar major-accident hazards involving dangerous substances		t and of the Council on the control of

Not applicable

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

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

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0	Other ir	nformation	:		ges have been made to the previous version the body of this document by two vertical	
F	ull tex	t of H-Statements				
H H	H302 H314 H318 H373		:	Harmful if swallowed. Causes severe skin burns and eye damage. Causes serious eye damage. May cause damage to organs through prolonged or repeated exposure if swallowed.		
F	ull tex	t of other abbreviation	ons			
E S S	Acute T Eye Da Skin Co STOT F E OEL	m. orr. RE	:	Ireland. List of Ch	age gan toxicity - repeated exposure emical Agents and Carcinogens with Occu- e Limit Values - Code of Practice, Schedule 1	
IE	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 - (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; TRGS - Technical Rule for Hazardous Substances; TSCA

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



Ertugliflozin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	2338808-00018	Date of first issue: 13.12.2017

- Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

Classification of the mixture:		Classification procedure:
Eye Dam. 1	H318	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.

IE / EN