

SAFETY DATA SHEET

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: 28.09.2024
5.0 14.04.2025 2338804-00019 Date of first issue: 13.12.2017

SECTION 1: Identifi

Relevant identified uses of the substance or mixture

Recommended restrictions : Not applicable

1.3 Details of the supplier of the safety data sheet

Details of the supplier of the safety data sheet
Company : MSD
Kilsheelan
Cloonmel Tipperary IE

Telephone : 353-51-601000

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)

Classification (EC 2010/653, Annex VI): H318: Causes serious eye damage

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Labelling (REACH)



Signal word : Danger

Hazard statements : H318 Causes serious eye damage.

Precautionary statements : P 111

SAFETY DATA SHEET

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



Ertugliflozin Formulation

Version
5.0

Revision Date:
14.04.2025

SDS Number:
2338804-00019

Date of last issue: 28.09.2024
Date of first issue: 13.12.2017

P280 Wear eye protection/ face protection.

Response:

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. 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.

SAFETY DATA SHEET

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



Ertugliflozin Formulation

Version
5.0

Revision Date:
14.04.2025

SDS Number:
2338804-00019

Date of last issue: 28.09.2024
Date of first issue: 13.12.2017

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.
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. Get medical attention if symptoms occur.
In case of skin contact	: Wash with water and soap. Get medical attention if symptoms occur.
In case of eye contact	: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately.
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	: Contact with dust can cause mechanical irritation or drying of the skin. Causes serious eye damage.
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4.3 Indication of any immediate medical attention and special treatment needed

Treatment	: Treat symptomatically and supportively.
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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	: None known.

SAFETY DATA SHEET

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



Ertugliflozin Formulation

Version
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Revision Date:
14.04.2025

SDS Number:
2338804-00019

Date of last issue: 28.09.2024
Date of first issue: 13.12.2017

5.2 Special hazards arising from the 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 products : Carbon oxides
Metal oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances 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 protective 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 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.

SAFETY DATA SHEET

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



Ertugliflozin Formulation

Version
5.0

Revision Date:
14.04.2025

SDS Number:
2338804-00019

Date of last issue: 28.09.2024
Date of first issue: 13.12.2017

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	: Do not breathe dust. Do not swallow. Do not get in 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 assessment 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 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 contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	: Keep in properly labelled containers. Keep tightly closed. Store in accordance 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
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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

SAFETY DATA SHEET

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: 28.09.2024
5.0 14.04.2025 2338804-00019 Date of first issue: 13.12.2017

Dust	5 mg/m ³ Value type (Form of exposure): TWA (respirable dust) Basis: FOR-2011-12-06-1358
	10 mg/m ³ Value type (Form of exposure): TWA (total dust) Basis: FOR-2011-12-06-1358

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ertugliflozin	1210344-83-4	TWA	10 µg/m ³ (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	: Consider double gloving.
Skin and body protection	: 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	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS 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

SAFETY DATA SHEET

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



Ertugliflozin Formulation

Version 5.0	Revision Date: 14.04.2025	SDS Number: 2338804-00019	Date of last issue: 28.09.2024 Date of first issue: 13.12.2017
----------------	------------------------------	------------------------------	---

Colour : No data available

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, handling 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 : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity
Viscosity, kinematic : Not applicable

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : Not applicable

Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Particle characteristics
Particle size : No data available

SAFETY DATA SHEET

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



Ertugliflozin Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 2338804-00019 Date of last issue: 28.09.2024
Date of first issue: 13.12.2017

9.2 Other information

Explosives : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
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, handling or other means.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

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

Information on likely routes of exposure : Inhalation
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:

SAFETY DATA SHEET

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



Ertugliflozin Formulation

Version 5.0	Revision Date: 14.04.2025	SDS Number: 2338804-00019	Date of last issue: 28.09.2024 Date of first issue: 13.12.2017
----------------	------------------------------	------------------------------	---

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

Skin corrosion/irritation

||| Not classified based on available information.

Product:

Assessment	:	No skin irritation
Method	:	EpiDerm
Result	:	Not corrosive

Components:

Ertugliflozin:

||| Result : Corrosive

Serious eye damage/eye irritation

||| Causes serious eye damage.

Components:

Ertugliflozin:

||| Result : Severe irritation

Respiratory or skin sensitisation

Skin sensitisation

||| Not classified based on available information.

Respiratory sensitisation

||| Not classified based on available information.

Components:

Ertugliflozin:

||| Test Type : Local lymph node assay (LLNA)
||| Result : Not a skin sensitizer.

Germ cell mutagenicity

||| Not classified based on available information.

Components:

Ertugliflozin:

||| Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
||| Result: negative
||| Test Type: Chromosome aberration test in vitro

SAFETY DATA SHEET

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



Ertugliflozin Formulation

Version
5.0

Revision Date:
14.04.2025

SDS Number:
2338804-00019

Date of last issue: 28.09.2024
Date of first issue: 13.12.2017



Result: negative

Genotoxicity in vivo

: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Ertugliflozin:

Species
Application Route
Exposure time
Result

: Mouse
: Oral
: 2 Years
: negative

Species
Application Route
Exposure time
Result

: Rat
: Oral
: 2 Years
: negative

Carcinogenicity - Assessment

: Weight of evidence does not support classification as a carcinogen

Reproductive toxicity

Not classified based on available information.

Components:

Ertugliflozin:

Effects on fertility

: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Fertility: NOAEL: 250 mg/kg body weight
Remarks: Maternal toxicity observed.
No significant adverse effects were reported

Test Type: Fertility/early embryonic development
Species: Rabbit
Application Route: Oral
Fertility: NOAEL: 200 mg/kg body weight
Remarks: No significant adverse effects were reported

Effects on foetal development

: Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 50 mg/kg body weight
Remarks: Adverse developmental effects were observed

Test Type: Embryo-foetal development

SAFETY DATA SHEET

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



Ertugliflozin Formulation

Version
5.0

Revision Date:
14.04.2025

SDS Number:
2338804-00019

Date of last issue: 28.09.2024
Date of first issue: 13.12.2017

Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 250 mg/kg body weight
Remarks: No significant adverse effects were reported

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

Ertugliflozin:

Exposure routes	:	Oral
Target Organs	:	Kidney, Stomach, Prostate
Assessment	:	May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Ertugliflozin:

Species	:	Rat
LOAEL	:	500 mg/kg
Application Route	:	Oral
Exposure time	:	30 d

Species	:	Rat
LOAEL	:	250 mg/kg
Application Route	:	Oral
Exposure time	:	30 d
Target Organs	:	Kidney

Species	:	Rat
LOAEL	:	25 mg/kg
Application Route	:	Oral
Exposure time	:	180 d
Target Organs	:	Kidney, Bone, Stomach

Species	:	Rat
LOAEL	:	25 mg/kg
Exposure time	:	90 d
Target Organs	:	Kidney, Gastrointestinal tract, Prostate

Species	:	Dog
NOAEL	:	150 mg/kg
Application Route	:	Oral
Exposure time	:	270 d
Remarks	:	No significant adverse effects were reported

Species	:	Mouse
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SAFETY DATA SHEET

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



Ertugliflozin Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 2338804-00019 Date of last issue: 28.09.2024
Date of first issue: 13.12.2017

NOAEL	:	100 mg/kg
Application Route	:	Oral
Exposure time	:	90 d
Remarks	:	No significant adverse effects were reported

Species	:	Mouse
NOAEL	:	100 mg/kg
Application Route	:	Oral
Exposure time	:	28 d
Target Organs	:	Bone
Remarks	:	No significant adverse effects were reported

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Not classified based on available information.

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.
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Experience with human exposure

Components:

Ertugliflozin:

Ingestion	:	Symptoms: The most common side effects are:, Headache, constipation, Diarrhoea, Nausea, urinary tract infection, muscle pain, upper respiratory tract infection
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SECTION 12: Ecological information

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

SAFETY DATA SHEET

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



Ertugliflozin Formulation

Version 5.0	Revision Date: 14.04.2025	SDS Number: 2338804-00019	Date of last issue: 28.09.2024 Date of first issue: 13.12.2017
----------------	------------------------------	------------------------------	---

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
Toxicity to fish (Chronic toxicity)	: NOEC: 1 mg/l Exposure time: 32 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210 Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC: 2,14 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility

12.2 Persistence and degradability

Components:

Ertugliflozin:

Biodegradability	: Result: Not readily biodegradable. Biodegradation: 40,8 % Exposure time: 28 d
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12.3 Bioaccumulative potential

Components:

Ertugliflozin:

Partition coefficient: n-octanol/water	: log Pow: 2,47
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12.4 Mobility in soil

Components:

Ertugliflozin:

Distribution among environmental compartments	: log Koc: 2,88
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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.
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SAFETY DATA SHEET

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



Ertugliflozin Formulation

Version
5.0

Revision Date:
14.04.2025

SDS Number:
2338804-00019

Date of last issue: 28.09.2024
Date of first issue: 13.12.2017

12.6 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.

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 handling 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

IATA

: 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

IATA

: Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN

: Not regulated as a dangerous good

SAFETY DATA SHEET

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



Ertugliflozin Formulation

Version 5.0	Revision Date: 14.04.2025	SDS Number: 2338804-00019	Date of last issue: 28.09.2024 Date of first issue: 13.12.2017
----------------	------------------------------	------------------------------	---

ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

14.4 Packing group

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
IATA (Cargo)	:	Not regulated as a dangerous good
IATA (Passenger)	:	Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks	:	Not applicable for product as supplied.
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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
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Regulation (EU) No 2024/590 on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	:	Not applicable
Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals	:	Not applicable
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.		
		Not applicable

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

AICS	:	not determined
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SAFETY DATA SHEET

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



Ertugliflozin Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 2338804-00019 Date of last issue: 28.09.2024
Date of first issue: 13.12.2017

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H302 : Harmful if swallowed.
H314 : Causes severe skin burns and eye damage.
H318 : Causes serious eye damage.
H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Eye Dam. : Serious eye damage
Skin Corr. : Skin corrosion
STOT RE : Specific target organ toxicity - repeated exposure
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / : Long term exposure limit
TWA

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 sub-

SAFETY DATA SHEET

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



Ertugliflozin Formulation

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stance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

Classification of the mixture:

Eye Dam. 1 H318

Classification procedure:

Calculation method

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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NO / FN