

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ertugliflozin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
7.0	04/14/2025	2337987-00018	Date of first issue: 12/13/2017

SECTION 1. IDENTIFICATION

Product name : Ertugliflozin Formulation

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 accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Serious eye damage : Category 1

Specific target organ toxicity : Category 2 (Kidney, Stomach, Prostate)
- repeated exposure (Oral)

Other hazards

Contact with dust can cause mechanical irritation or drying of the skin.

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H318 Causes serious eye damage.
H373 May cause damage to organs (Kidney, Stomach, Prostate) through prolonged or repeated exposure if swallowed.

Supplemental Hazard Statements : Corrosive to the respiratory tract.

Precautionary Statements : **Prevention:**
P260 Do not breathe dust.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ertugliflozin Formulation

Version 7.0 Revision Date: 04/14/2025 SDS Number: 2337987-00018 Date of last issue: 09/28/2024
Date of first issue: 12/13/2017

P280 Wear eye protection and 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.

P314 Get medical attention if you feel unwell.

Disposal:

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Cellulose	9004-34-6*	>= 45 - <= 70	TSC
Ertugliflozin	1210344-83-4*	>= 3 - <= 7	TSC
Titanium dioxide	13463-67-7*	>= 0.5 - <= 1.5	TSC

* Indicates that the identifier is a CAS No.

TSC- the 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.
- 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.
- Most important symptoms and effects, both acute and delayed : Contact with dust can cause mechanical irritation or drying of the skin.
Causes serious eye damage.
May cause damage to organs through prolonged or repeated exposure if swallowed.
Corrosive to the respiratory tract.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ertugliflozin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
7.0	04/14/2025	2337987-00018	Date of first issue: 12/13/2017

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 Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	:	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.
Hazardous combustion products	:	Carbon oxides Metal oxides
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.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency 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.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ertugliflozin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
7.0	04/14/2025	2337987-00018	Date of first issue: 12/13/2017

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.
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. |
| Conditions for safe storage | : | Keep in properly labeled containers.
Keep tightly closed.
Store in accordance with the particular national regulations. |
| Materials to avoid | : | Do not store with the following product types:
Strong oxidizing agents |

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

inert or nuisance dust	50 Million particles per cubic foot Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3
	15 mg/m ³ Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3
	5 mg/m ³ Value type (Form of exposure): TWA (respirable fraction) Basis: OSHA Z-3
	15 Million particles per cubic foot Value type (Form of exposure): TWA (respirable fraction)

Ertugliflozin Formulation

Version 7.0 Revision Date: 04/14/2025 SDS Number: 2337987-00018 Date of last issue: 09/28/2024
Date of first issue: 12/13/2017

	Basis: OSHA Z-3
Dust, nuisance dust and particulates	10 mg/m ³ Value type (Form of exposure): PEL (Total dust) Basis: CAL PEL
	5 mg/m ³ Value type (Form of exposure): PEL (respirable dust fraction) Basis: CAL PEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
Ertugliflozin	1210344-83-4	TWA	10 µg/m ³ (OEB 3)	Internal
		Wipe limit	100 µg/100 cm ²	Internal
Titanium dioxide	13463-67-7	TWA (Respirable particulate matter)	2.5 mg/m ³ (Titanium dioxide)	ACGIH
		TWA (total dust)	15 mg/m ³	OSHA Z-1

This substance(s) is not bioavailable and therefore does not contribute to a dust inhalation hazard.

Titanium dioxide

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

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ertugliflozin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
7.0	04/14/2025	2337987-00018	Date of first issue: 12/13/2017

supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye 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.

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.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form explosive dust-air mixture during processing,

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ertugliflozin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
7.0	04/14/2025	2337987-00018	Date of first issue: 12/13/2017

	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
Vapor pressure	: Not applicable
Relative vapor density	: Not applicable
Relative density	: No data available
Density	: No data available
Solubility(ies) Water solubility	: No data available
Partition coefficient: n-octanol/water	: Not applicable
Autoignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity Viscosity, kinematic	: Not applicable
Explosive properties	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.
Particle characteristics Particle size	: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: Not classified as a reactivity hazard.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: 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.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ertugliflozin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
7.0	04/14/2025	2337987-00018	Date of first issue: 12/13/2017

SECTION 11. TOXICOLOGICAL INFORMATION

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: > 5,000 mg/kg
Method: Calculation method

Components:

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Ertugliflozin:

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

Titanium dioxide:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

Skin corrosion/irritation

|| Not classified based on available information.

Product:

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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ertugliflozin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
7.0	04/14/2025	2337987-00018	Date of first issue: 12/13/2017

Components:

Ertugliflozin:

|| Result : Corrosive

Titanium dioxide:

|| Species : Rabbit
|| Result : No skin irritation

Serious eye damage/eye irritation

|| Causes serious eye damage.

Components:

Ertugliflozin:

|| Result : Severe irritation

Titanium dioxide:

|| Species : Rabbit
|| Result : No eye irritation

Respiratory or skin sensitization

Skin sensitization

|| Not classified based on available information.

Respiratory sensitization

|| Not classified based on available information.

Components:

Ertugliflozin:

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

Titanium dioxide:

|| Test Type : Local lymph node assay (LLNA)
|| Routes of exposure : Skin contact
|| Species : Mouse
|| Result : negative

Germ cell mutagenicity

|| Not classified based on available information.

Components:

Cellulose:

|| Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
|| Result: negative
|| Test Type: In vitro mammalian cell gene mutation test

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ertugliflozin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
7.0	04/14/2025	2337987-00018	Date of first issue: 12/13/2017

	Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative

Ertugliflozin:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: Chromosome aberration test in vitro Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Rat Result: negative

Titanium dioxide:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	: Test Type: In vivo micronucleus test Species: Mouse Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Cellulose:

Species	: Rat
Application Route	: Ingestion
Exposure time	: 72 weeks
Result	: negative

Ertugliflozin:

Species	: Mouse
Application Route	: Oral
Exposure time	: 2 Years
Result	: negative

Species	: Rat
Application Route	: Oral
Exposure time	: 2 Years
Result	: negative

Carcinogenicity - Assess-	: Weight of evidence does not support classification as a car-
---------------------------	--

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ertugliflozin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
7.0	04/14/2025	2337987-00018	Date of first issue: 12/13/2017

|| ment cinogen

Titanium dioxide:

Species : Rat
Application Route : inhalation (dust/mist/fume)
Exposure time : 2 Years
Method : OECD Test Guideline 453
Result : positive
Remarks : The mechanism or mode of action may not be relevant in humans.
This substance(s) is not bioavailable and therefore does not contribute to a dust inhalation hazard.

|| Carcinogenicity - Assessment : Limited evidence of carcinogenicity in inhalation studies with animals.

|| IARC Group 2B: Possibly carcinogenic to humans
Titanium dioxide 13463-67-7

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

|| Not classified based on available information.

Components:

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative
Effects on fetal development : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ertugliflozin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
7.0	04/14/2025	2337987-00018	Date of first issue: 12/13/2017

Effects on fetal development	:	Fertility: NOAEL: 200 mg/kg body weight
	:	Remarks: No significant adverse effects were reported
	:	Test Type: Embryo-fetal development
	:	Species: Rat
	:	Application Route: Oral
	:	Developmental Toxicity: NOAEL: 50 mg/kg body weight
	:	Remarks: Adverse developmental effects were observed
	:	Test Type: Embryo-fetal development
	:	Species: Rabbit
	:	Application Route: Oral
	:	Developmental Toxicity: NOAEL: 250 mg/kg body weight
	:	Remarks: No significant adverse effects were reported

STOT-single exposure

Corrosive to the respiratory tract.

STOT-repeated exposure

May cause damage to organs (Kidney, Stomach, Prostate) through prolonged or repeated exposure if swallowed.

Components:

Ertugliflozin:

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

Repeated dose toxicity

Components:

Cellulose:

Species	:	Rat
NOAEL	:	>= 9,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days

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
---------	---	-----

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ertugliflozin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
7.0	04/14/2025	2337987-00018	Date of first issue: 12/13/2017

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
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

Titanium dioxide:

Species	: Rat
NOAEL	: 24,000 mg/kg
Application Route	: Ingestion
Exposure time	: 28 Days

Species	: Rat
NOAEL	: 10 mg/m ³
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 2 y

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Ertugliflozin:

Ingestion	: Symptoms: The most common side effects are:, Headache, constipation, Diarrhea, Nausea, urinary tract infection, muscle pain, upper respiratory tract infection
-----------	--

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ertugliflozin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
7.0	04/14/2025	2337987-00018	Date of first issue: 12/13/2017

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:

Toxicity to fish	: LC50 (<i>Oryzias latipes</i> (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
------------------	--

Ertugliflozin:

Toxicity to algae/aquatic plants	: EC50 (<i>Pseudokirchneriella subcapitata</i> (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 fish (Chronic toxicity)	: NOEC (<i>Pimephales promelas</i> (fathead minnow)): 1 mg/l Exposure time: 32 d Method: OECD Test Guideline 210 Remarks: No toxicity at the limit of solubility.
-------------------------------------	---

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (<i>Daphnia magna</i> (Water flea)): 2.14 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility.
--	--

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

Titanium dioxide:

Toxicity to fish	: LC50 (<i>Oncorhynchus mykiss</i> (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
------------------	--

Toxicity to daphnia and other aquatic invertebrates	: EC50 (<i>Daphnia magna</i> (Water flea)): > 100 mg/l Exposure time: 48 h
---	--

Toxicity to algae/aquatic plants	: EC50 (<i>Skeletonema costatum</i> (marine diatom)): > 10,000 mg/l Exposure time: 72 h
----------------------------------	---

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ertugliflozin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
7.0	04/14/2025	2337987-00018	Date of first issue: 12/13/2017

|| Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Persistence and degradability

Components:

Cellulose:

|| Biodegradability : Result: Readily biodegradable.

Ertugliflozin:

|| Biodegradability : Result: Not readily biodegradable.
Biodegradation: 40.8 %
Exposure time: 28 d

Bioaccumulative potential

Components:

Ertugliflozin:

|| Partition coefficient: n-octanol/water : log Pow: 2.47

Mobility in soil

Components:

Ertugliflozin:

|| Distribution among environmental compartments : log Koc: 2.88

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
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

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ertugliflozin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
7.0	04/14/2025	2337987-00018	Date of first issue: 12/13/2017

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Domestic regulation

49 CFR

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Combustible dust
Specific target organ toxicity (single or repeated exposure)
Serious eye damage or eye irritation

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

Cellulose	9004-34-6
D-Glucose, 4-O-β-D-galactopyranosyl-, monohydrate	64044-51-5
Ertugliflozin	1210344-83-4

California Prop. 65

WARNING: This product can expose you to chemicals including Titanium dioxide, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California Permissible Exposure Limits for Chemical Contaminants

Cellulose	9004-34-6
-----------	-----------

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

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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



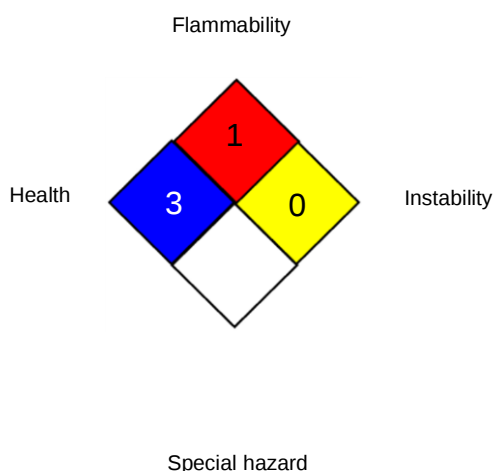
Ertugliflozin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
7.0	04/14/2025	2337987-00018	Date of first issue: 12/13/2017

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:

HEALTH	*	3
FLAMMABILITY		3
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CAL PEL	:	California permissible exposure limits for chemical contaminants (Title 8, Article 107)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA	:	8-hour, time-weighted average
CAL PEL / PEL	:	Permissible exposure limit
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA	:	8-hour time weighted average
OSHA Z-3 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ertugliflozin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
7.0	04/14/2025	2337987-00018	Date of first issue: 12/13/2017

- 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECL - 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

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 Agency, <http://echa.europa.eu/>

Revision Date : 04/14/2025

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

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.

US / Z8