

# **Ertugliflozin / Metformin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.2
 06.04.2024
 590544-00019
 Date of first issue: 01.04.2016

**SECTION 1: IDENTIFICATION** 

Product name : Ertugliflozin / Metformin Formulation

Manufacturer or supplier's details

Company : MSD

Address : Building A - Level 1/26 Talavera Rd

Macquarie Park NSW, Australia 2113

Telephone : 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

### **SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification** 

Acute toxicity (Oral) : Category 4

**GHS** label elements

Hazard pictograms

Signal word : Warning

Hazard statements : H302 Harmful if swallowed.

Precautionary statements : Prevention:

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.



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#### Other hazards which do not result in classification

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           | CAS-No.      | Concentration (% w/w) |  |
|-------------------------|--------------|-----------------------|--|
| metformin hydrochloride | 1115-70-4    | >= 60 -<= 100         |  |
| Cellulose               | 9004-34-6    | >= 10 -< 30           |  |
| Magnesium stearate      | 557-04-0     | < 10                  |  |
| Ertugliflozin           | 1210344-83-4 | < 1                   |  |

#### **SECTION 4. FIRST AID MEASURES**

General advice In the case of accident or if you feel unwell, seek medical ad-

vice 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 If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting unless directed to do

so by medical personnel. Get medical attention.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

Most important symptoms

and effects, both acute and

delaved

Harmful if swallowed.

Contact with dust can cause mechanical irritation or drying of

Dust contact with the eyes can lead to mechanical irritation. Protection of first-aiders First Aid responders should pay attention to self-protection.

and use the recommended personal protective equipment

when the potential for exposure exists (see section 8).

Treat symptomatically and supportively. Notes to physician

#### **SECTION 5. FIREFIGHTING MEASURES**

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

None known.

Specific hazards during fire-Avoid generating dust; fine dust dispersed in air in sufficient



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concentrations, and in the presence of an ignition source is a fighting

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective 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 pro-

tective 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 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 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 deter-

mine 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.

Do not breathe dust. Advice on safe handling



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Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

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. Do not eat, drink or smoke when using this product.

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.

Conditions for safe storage : Keep in properly labelled containers.

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**

## Components with workplace control parameters

| Components              | CAS-No.          | Value type<br>(Form of<br>exposure)                | Control parameters / Permissible concentration | Basis    |
|-------------------------|------------------|--|--|----------|
| metformin hydrochloride | 1115-70-4        | TWA  | 1 mg/m3 (OEB 1)                                | Internal |
| Cellulose               | 9004-34-6        | TWA  | 10 mg/m3                                       | AU OEL   |
|                         |                  | TWA  | 10 mg/m3                                       | ACGIH    |
| Magnesium stearate      | 557-04-0         | TWA  | 10 mg/m3                                       | AU OEL   |
|                         |                  | TWA (Inhal-<br>able particu-<br>late matter)       | 10 mg/m3                                       | ACGIH    |
|                         |                  | TWA (Res-<br>pirable par-<br>ticulate mat-<br>ter) | 3 mg/m3  | ACGIH    |
| Ertugliflozin           | 1210344-83-<br>4 | TWA  | 10 μg/m3 (OEB 3)                               | Internal |
|                         |                  | Wipe limit   | 100 μg/100 cm <sup>2</sup>                     | Internal |



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**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 con-

tainment devices).

Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Particulates type

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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : powder

Colour : No data available

Odour : No data available

Odour 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



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

dling 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

Vapour pressure : Not applicable

Relative vapour 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

Auto-ignition 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 reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials : Oxidizing agents



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Hazardous decomposition

products

No hazardous decomposition products are known.

### **SECTION 11. TOXICOLOGICAL INFORMATION**

Exposure routes : Inhalation

Skin contact Ingestion Eye contact

**Acute toxicity** 

Harmful if swallowed.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: 1,337 mg/kg

Method: Calculation method

**Components:** 

metformin hydrochloride:

Acute oral toxicity : LD50 (Rat): 1,000 mg/kg

LD50 (Mouse): 1,450 - 3,500 mg/kg

LD50 (Monkey): 463 mg/kg

LD50 (Rabbit): 350 mg/kg

LD50 (Guinea pig): 500 mg/kg

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

Magnesium stearate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 423

Assessment: The substance or mixture has no acute oral tox-

icity

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Remarks: Based on data from similar materials

**Ertugliflozin:** 



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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.

### **Components:**

### metformin hydrochloride:

Species : Rabbit

Result : Mild skin irritation

### Magnesium stearate:

Species : Rabbit

Result : No skin irritation

Remarks : Based on data from similar materials

**Ertugliflozin:** 

Result : Corrosive

#### Serious eye damage/eye irritation

Not classified based on available information.

### **Components:**

#### metformin hydrochloride:

Species : Rabbit

Result : Mild eye irritation

### Magnesium stearate:

Species : Rabbit

Result : No eye irritation

Remarks : Based on data from similar materials

**Ertugliflozin:** 

Result : Severe irritation

## Respiratory or skin sensitisation

## Skin sensitisation

Not classified based on available information.

## Respiratory sensitisation

Not classified based on available information.



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### Components:

Magnesium stearate:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials

**Ertugliflozin:** 

Test Type : Local lymph node assay (LLNA)

Result : Not a skin sensitizer.

**Chronic toxicity** 

Germ cell mutagenicity

Not classified based on available information.

Components:

metformin hydrochloride:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: in vitro assay

Test system: mouse lymphoma cells

Result: negative

Test Type: Chromosomal aberration Test system: Human lymphocytes

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Application Route: Oral

Result: negative

Cellulose:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative



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Magnesium stearate:

Genotoxicity in vitro Test Type: In vitro mammalian cell gene mutation test

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

**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

Carcinogenicity

Not classified based on available information.

**Components:** 

metformin hydrochloride:

Species Mouse Exposure time 91 weeks

Dose 1500 mg/kg body weight

Result negative

Rat. male Species **Application Route** Oral Exposure time 104 weeks

Dose 900 mg/kg body weight

Result negative

Species Rat, female

Application Route Oral Exposure time

104 weeks

LOAEL 900 mg/kg body weight

Result negative

**Target Organs** Uterus (including cervix)

Remarks The mechanism or mode of action may not be relevant in hu-

mans.



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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 2 Years Exposure time Result negative

Carcinogenicity - Assess-

cinogen ment

Reproductive toxicity

Not classified based on available information.

Components:

metformin hydrochloride:

Test Type: Fertility Effects on fertility

Species: Rat

Application Route: Oral

Fertility: NOAEL: 600 mg/kg body weight

Result: No effects on fertility

Effects on foetal develop-

ment

Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: NOAEL: 600 mg/kg body weight

Weight of evidence does not support classification as a car-

Result: No teratogenic effects

Test Type: Embryo-foetal development

Species: Rabbit Application Route: Oral

Embryo-foetal toxicity: NOAEL: 140 mg/kg body weight

Result: No teratogenic effects

Cellulose:

Effects on fertility Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative



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Effects on foetal develop-

ment

Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Magnesium stearate:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

**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 develop-

ment

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

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.



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### STOT - repeated exposure

Not classified based on available information.

#### Components:

### **Ertugliflozin:**

Exposure routes : Oral

Kidney, Stomach, Prostate Target Organs

May cause damage to organs through prolonged or repeated Assessment

exposure.

## Repeated dose toxicity

### **Components:**

## metformin hydrochloride:

**Species** Rat

NOAEL 125 mg/kg Application Route Oral Exposure time 1 year

Remarks No significant adverse effects were reported

Species Rabbit **NOAEL** 100 mg/kg Application Route Oral Exposure time

Remarks No significant adverse effects were reported

Species Dog NOAEL 50 mg/kg Application Route : Subcutaneous

Exposure time : 2 year

Remarks : No significant adverse effects were reported

### Cellulose:

**Species** Rat

NOAEL >= 9,000 mg/kgApplication Route : Ingestion : 90 Days

Exposure time

## Magnesium stearate:

**Species** : Rat

: > 100 mg/kgNOAEL Application Route : Ingestion 90 Davs Exposure time

Remarks Based on data from similar materials

## **Ertugliflozin:**

**Species** Rat LOAEL 500 mg/kg



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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
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.

### **Experience with human exposure**

## **Components:**

### metformin hydrochloride:

Skin contact : Remarks: May irritate skin. Eye contact : Remarks: May irritate eyes.

Ingestion : Symptoms: Diarrhoea, Nausea, Vomiting, Gastrointestinal

discomfort, flatulence, asthenia, Fatigue, Headache

### Ertugliflozin:



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Ingestion : Symptoms: The most common side effects are:, Headache,

constipation, Diarrhoea, Nausea, urinary tract infection, mus-

cle pain, upper respiratory tract infection

#### **SECTION 12. ECOLOGICAL INFORMATION**

### **Ecotoxicity**

### **Components:**

metformin hydrochloride:

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 10 mg/l

Exposure time: 33 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 40 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Magnesium stearate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l

Exposure time: 48 h Method: DIN 38412

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 1 mg/l

Exposure time: 47 h

Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.2. Remarks: Based on data from similar materials

No toxicity at the limit of solubility



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Toxicity to algae/aquatic

plants

: EL50 (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

No toxicity at the limit of solubility

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 100 mg/l

Exposure time: 16 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

**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 fish (Chronic tox-

icity)

NOEC (Pimephales promelas (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 (Chron-

ic toxicity)

NOEC (Daphnia magna (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



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Persistence and degradability

**Components:** 

metformin hydrochloride:

Biodegradability Result: rapidly degradable

> Biodegradation: 50 % Exposure time: 2 hrs

Cellulose:

Biodegradability Result: Readily biodegradable.

Magnesium stearate:

Biodegradability Result: Not biodegradable

Remarks: Based on data from similar materials

**Ertugliflozin:** 

Biodegradability Result: Not readily biodegradable.

> Biodegradation: 40.8 % Exposure time: 28 d

**Bioaccumulative potential** 

**Components:** 

metformin hydrochloride:

Partition coefficient: n-

octanol/water

log Pow: -2

Magnesium stearate:

Partition coefficient: n-

octanol/water

log Pow: > 4

**Ertugliflozin:** 

Partition coefficient: n-

octanol/water

log Pow: 2.47

Mobility in soil

**Components:** 

metformin hydrochloride:

Distribution among environ-

log Koc: 4.3

mental compartments

Method: OECD Test Guideline 106

**Ertugliflozin:** 

Distribution among environ-

mental compartments

log Koc: 2.88



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#### Other adverse effects

No data available

#### **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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### **SECTION 14. TRANSPORT INFORMATION**

### International Regulations

**UNRTDG** 

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo : Not applicable

aircraft)

Packing instruction (passen- : Not applicable

ger aircraft)

**IMDG-Code** 

**UN** number Not applicable Proper shipping name Not applicable Not applicable Class Not applicable Subsidiary risk Packing group Not applicable Labels Not applicable **EmS Code** Not applicable Marine pollutant Not applicable

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

Not applicable for product as supplied.

### **National Regulations**

**ADG** 



## **Ertugliflozin / Metformin Formulation**

Revision Date: SDS Number: Date of last issue: 30.09.2023 Version 590544-00019 4.2 06.04.2024 Date of first issue: 01.04.2016

**UN** number Not applicable Not applicable Proper shipping name Class Not applicable Subsidiary risk Not applicable Not applicable Packing group Not applicable Labels Hazchem Code Not applicable

Special precautions for user

Not applicable

#### **SECTION 15. REGULATORY INFORMATION**

Safety, health and environmental regulations/legislation specific for the substance or mix-

Therapeutic Goods (Poisons:

Standard) Instrument

Schedule 6 (Please use the original publication to check for specific uses, specific conditions or threshold limits that might

apply for this chemical)

Prohibition/Licensing Requirements There is no applicable prohibition,

authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regula-

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

**AICS** not determined

**DSL** not determined

**IECSC** not determined

### **SECTION 16: ANY OTHER RELEVANT INFORMATION**

**Further information** 

: 06.04.2024 Revision Date

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 Agen-

cy, http://echa.europa.eu/

Date format dd.mm.yyyy

Full text of other abbreviations

**ACGIH** USA. ACGIH Threshold Limit Values (TLV)

AU OEL Australia. Workplace Exposure Standards for Airborne Con-

taminants.

ACGIH / TWA 8-hour, time-weighted average

AU OEL / TWA Exposure standard - time weighted average



## **Ertugliflozin / Metformin Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.2 06.04.2024 590544-00019 Date of first issue: 01.04.2016

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, 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

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.

AU / EN