

Ertugliflozin / Metformin Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 3.1 2023/09/30 590553-00018 Date of first issue: 2016/04/01

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ertugliflozin / Metformin Formulation

Manufacturer or supplier's details

Company : MSD

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000

Emergency telephone number : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

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.



Ertugliflozin / Metformin Formulation

Version SDS Number: Date of last issue: 2023/04/04 Revision Date: 3.1 2023/09/30 590553-00018 Date of first issue: 2016/04/01

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.

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

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.

: If in eyes, rinse well with water. In case of eye contact

Get medical attention if irritation develops and persists.

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

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

Protection of first-aiders

delayed

Harmful if swallowed.

Contact with dust can cause mechanical irritation or drying of

the skin.

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

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing None known.



Ertugliflozin / Metformin Formulation

SDS Number: Date of last issue: 2023/04/04 Version Revision Date: 3.1 2023/09/30 590553-00018 Date of first issue: 2016/04/01

media

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 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.

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.

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.



Ertugliflozin / Metformin Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 3.1 2023/09/30 590553-00018 Date of first issue: 2016/04/01

Advice on safe handling : Do not breathe dust.

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.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
metformin hydrochloride	1115-70-4	TWA	1 mg/m3 (OEB 1)	Internal
Cellulose	9004-34-6	NAB	10 mg/m3	ID OEL
		TWA	10 mg/m3	ACGIH
Magnesium stearate	557-04-0	NAB	10 mg/m3	ID OEL
	Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals			
		TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
Ertugliflozin	1210344-83- 4	TWA	10 μg/m3 (OEB 3)	Internal
		Wipe limit	100 μg/100 cm ²	Internal

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-



Ertugliflozin / Metformin Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 3.1 2023/09/30 590553-00018 Date of first issue: 2016/04/01

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

Hand protection

Particulates type

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.

Hygiene measures : If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the work-

ing 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.

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



Ertugliflozin / Metformin Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 3.1 2023/09/30 590553-00018 Date of first issue: 2016/04/01

Flash point : Not applicable

Evaporation rate : Not applicable

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 size : No data available

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.



Ertugliflozin / Metformin Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 3.1 2023/09/30 590553-00018 Date of first issue: 2016/04/01

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition : No haz

products

No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

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-

city

Remarks: Based on data from similar materials

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

Remarks: Based on data from similar materials



Ertugliflozin / Metformin Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 3.1 2023/09/30 590553-00018 Date of first issue: 2016/04/01

Ertugliflozin:

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.



Ertugliflozin / Metformin Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 3.1 2023/09/30 590553-00018 Date of first issue: 2016/04/01

Respiratory sensitisation

Not classified based on available information.

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.

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



Ertugliflozin / Metformin Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 3.1 2023/09/30 590553-00018 Date of first issue: 2016/04/01

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

Species : Rat, male
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-



Ertugliflozin / Metformin Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 3.1 2023/09/30 590553-00018 Date of first issue: 2016/04/01

mans.

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-

ment

Weight of evidence does not support classification as a car-

cinogen

Reproductive toxicity

Not classified based on available information.

Components:

metformin hydrochloride:

Effects on fertility : Test Type: 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

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



Ertugliflozin / Metformin Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 3.1 2023/09/30 590553-00018 Date of first issue: 2016/04/01

Result: negative

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.



Ertugliflozin / Metformin Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 3.1 2023/09/30 590553-00018 Date of first issue: 2016/04/01

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:

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 : 1 Year

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/kg
Application Route : Ingestion

Exposure time : 90 Days

Magnesium stearate:

Species : Rat

NOAEL : > 100 mg/kg Application Route : Ingestion Exposure time : 90 Days

Remarks : Based on data from similar materials

Ertugliflozin:

Species : Rat LOAEL : 500 mg/kg



Ertugliflozin / Metformin Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 3.1 2023/09/30 590553-00018 Date of first issue: 2016/04/01

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:



Ertugliflozin / Metformin Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 3.1 2023/09/30 590553-00018 Date of first issue: 2016/04/01

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

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

cle pain, upper respiratory tract infection

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



Ertugliflozin / Metformin Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 3.1 2023/09/30 590553-00018 Date of first issue: 2016/04/01

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



Ertugliflozin / Metformin Formulation

Version **Revision Date:** SDS Number: Date of last issue: 2023/04/04 590553-00018 3.1 2023/09/30 Date of first issue: 2016/04/01

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



Ertugliflozin / Metformin Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 3.1 2023/09/30 590553-00018 Date of first issue: 2016/04/01

Other adverse effects

No data available

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.

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

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 Class Not applicable Not applicable Subsidiary risk Not applicable Packing group 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.

Special precautions for user

Not applicable



Ertugliflozin / Metformin Formulation

SDS Number: Date of last issue: 2023/04/04 Version Revision Date: 3.1 2023/09/30 590553-00018 Date of first issue: 2016/04/01

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances **Hazardous to Health**

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Sub-

Hazardous substances approved for use Not applicable

Prohibited substances Not applicable

Restricted substances Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous **Materials**

Type of hazardous materials subject to distribution and : Not applicable

control, Annex I

Type of hazardous materials subject to distribution and : Not applicable

control, Annex II

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

AICS not determined

DSL not determined

IECSC not determined

16. OTHER INFORMATION

2023/09/30 **Revision Date**

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 Agen-

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

Date format yyyy/mm/dd

Full text of other abbreviations



Ertugliflozin / Metformin Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 3.1 2023/09/30 590553-00018 Date of first issue: 2016/04/01

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average ID OEL / NAB : Long term exposure limit

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.

ID / EN