

Ertugliflozin / Metformin Formulation

Version 4.1 Revision Date: 30.09.2023 SDS Number: 590563-00018 Date of last issue: 04.04.2023
Date of first issue: 01.04.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Trade name : Ertugliflozin / Metformin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
117 16th Road
1685 Halfway house, Midrand, South Africa

Telephone : +27 11 655 3000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Acute toxicity, Category 4

H302: Harmful if swallowed.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

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.

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Response:

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

Hazardous components which must be listed on the label:
metformin hydrochloride

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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**3.2 Mixtures****Components**

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|-------------------------|---|---|--------------------------|
| metformin hydrochloride | 1115-70-4 214-230-6 | Acute Tox. 4; H302 | >= 70 - < 90 |
| Ertugliflozin | 1210344-83-4 | Acute Tox. 4; H302 Skin Corr. 1B; H314 Eye Dam. 1; H318 STOT RE 2; H373 (Kidney, Stomach, Prostate) | >= 0,1 - < 1 |

For explanation of abbreviations see section 16.

SECTION 4: First aid measures**4.1 Description of first aid measures**

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

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- 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.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : 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.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

- Specific hazards during fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)
Metal oxides

5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.
Do not swallow.
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

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practice, based on the results of the workplace exposure assessment
 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
 Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|---|--------------|-------------------------------|------------------------------|----------|
| metformin hydrochloride | 1115-70-4 | TWA | 1 mg/m ³ (OEB 1) | Internal |
| Cellulose | 9004-34-6 | OEL-RL | 10 mg/m ³ | ZA OEL |
| Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents | | | | |
| Ertugliflozin | 1210344-83-4 | TWA | 10 µg/m ³ (OEB 3) | Internal |
| | | Wipe limit | 100 µg/100 cm ² | Internal |

8.2 Exposure controls

Engineering measures

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

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

Minimize open handling.

Personal protective equipment

| | | |
|--------------------------|---|--|
| Eye/face protection | : | Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. |
| Hand protection | : | |
| Material | : | Chemical-resistant gloves |
| Remarks | : | Consider double gloving. |
| Skin and body protection | : | Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing. |
| Respiratory protection | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. |
| Filter type | : | Particulates type (P) |

SECTION 9: Physical and chemical properties**9.1 Information on basic 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 |
| Flammability (solid, gas) | : | May form explosive dust-air mixture during processing, handling or other means. |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |

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| | | |
|--|---|--|
| 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. |

9.2 Other information

| | | |
|------------------------|---|-------------------|
| Flammability (liquids) | : | No data available |
| Particle size | : | No data available |

SECTION 10: Stability and reactivity**10.1 Reactivity**

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

| | | |
|---------------------|---|--|
| Hazardous reactions | : | May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents. |
|---------------------|---|--|

10.4 Conditions to avoid

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

10.5 Incompatible materials

| | | |
|--------------------|---|------------------|
| Materials to avoid | : | Oxidizing agents |
|--------------------|---|------------------|

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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SECTION 11: Toxicological information**11.1 Information on toxicological effects**

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

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

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Result : Corrosive

Serious eye damage/eye irritation

Not classified based on available information.

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Components:**metformin hydrochloride:**

Species : Rabbit
Result : Mild eye irritation

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Result : Severe irritation

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Ertugliflozin:**

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

Germ cell mutagenicity

Not classified based on available information.

Components:**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

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)

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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 humans.

Ertugliflozin:

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

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

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

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

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Result: No effects on fertility

Effects on foetal development : 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

Ertugliflozin:

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

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

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

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 250 mg/kg body weight
Remarks: No significant adverse effects were reported

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

Ertugliflozin:

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

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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

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

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

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

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

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

Species : Mouse
NOAEL : 100 mg/kg
Application Route : Oral

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| | | |
|-------------------|---|--|
| 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 |

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

SECTION 12: Ecological information**12.1 Toxicity****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 microorganisms | : | EC50 : > 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 |
| Toxicity to fish (Chronic toxicity) | : | NOEC: 10 mg/l Exposure time: 33 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210 |

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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 40 mg/l
 Exposure time: 21 d
 Species: Daphnia magna (Water flea)
 Method: OECD Test Guideline 211

Ertugliflozin:

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 77 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 50 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50 : > 1.000 mg/l
 Exposure time: 3 h
 Test Type: Respiration inhibition
 Method: OECD Test Guideline 209

NOEC : 1.000 mg/l
 Exposure time: 3 h
 Test Type: Respiration inhibition
 Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : NOEC: 1 mg/l
 Exposure time: 32 d
 Species: Pimephales promelas (fathead minnow)
 Method: OECD Test Guideline 210
 Remarks: No toxicity at the limit of solubility

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

12.2 Persistence and degradability

Components:

metformin hydrochloride:

Biodegradability : Result: rapidly degradable
 Biodegradation: 50 %
 Exposure time: 2 hrs

Ertugliflozin:

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

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12.3 Bioaccumulative potential

Components:

metformin hydrochloride:

Partition coefficient: n-octanol/water : log Pow: -2

Ertugliflozin:

Partition coefficient: n-octanol/water : log Pow: 2,47

12.4 Mobility in soil

Components:

metformin hydrochloride:

Distribution among environmental compartments : log Koc: 4,3
Method: OECD Test Guideline 106

Ertugliflozin:

Distribution among environmental compartments : log Koc: 2,88

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Product:

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

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SECTION 14: Transport information**14.1 UN number**

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

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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

14.4 Packing group

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

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SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

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

| | | |
|-------|---|----------------|
| AICS | : | not determined |
| DSL | : | not determined |
| IECSC | : | not determined |

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

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

Full text of other abbreviations

| | | |
|-----------------|---|--|
| Acute Tox. | : | Acute toxicity |
| Eye Dam. | : | Serious eye damage |
| Skin Corr. | : | Skin corrosion |
| STOT RE | : | Specific target organ toxicity - repeated exposure |
| ZA OEL | : | South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits |
| ZA OEL / OEL-RL | : | Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts) |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China;

Ertugliflozin / Metformin Formulation

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|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 4.1 | 30.09.2023 | 590563-00018 | Date of first issue: 01.04.2016 |

IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

Classification of the mixture:

Acute Tox. 4

H302

Classification procedure:

Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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