

Ertugliflozin (less than 2%) / Sitagliptin Formulation

Version 5.0 Revision Date: 04/12/2018 SDS Number: 595282-00007 Date of last issue: 02/01/2018
Date of first issue: 04/04/2016

SECTION 1. IDENTIFICATION

Product name : Ertugliflozin (less than 2%) / Sitagliptin Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc

Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033

Telephone : 908-740-4000

Telefax : 908-735-1496

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with 29 CFR 1910.1200**

Combustible dust

Skin irritation : Category 2

Eye irritation : Category 2A

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

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H373 May cause damage to organs (Kidney, Stomach, Prostate) through prolonged or repeated exposure if swallowed.

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Precautionary Statements : **Prevention:**
 P260 Do not breathe dust.
 P264 Wash skin thoroughly after handling.
 P280 Wear protective gloves/ eye protection/ face protection.

Response:
 P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P314 Get medical advice/ attention if you feel unwell.
 P332 + P313 If skin irritation occurs: Get medical advice/ attention.
 P337 + P313 If eye irritation persists: Get medical advice/ attention.
 P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:
 P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous ingredients

| Chemical name | CAS-No. | Concentration (% w/w) |
|--------------------|--------------|-----------------------|
| Sitagliptin | 654671-77-9 | >= 30 - < 50 |
| Cellulose | 9004-34-6 | >= 30 - < 50 |
| Ertugliflozin | 1210344-83-4 | >= 1 - < 3 |
| Magnesium stearate | 557-04-0 | >= 1 - < 5 |

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately., When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

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|---|---|--|
| In case of eye contact | : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention. |
| If swallowed | : | If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water. |
| Most important symptoms and effects, both acute and delayed | : | Causes skin irritation. Causes serious eye irritation. May cause damage to organs through prolonged or repeated exposure if swallowed. |
| 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. |
| Notes to physician | : | Treat symptomatically and supportively. |
-

SECTION 5. FIRE-FIGHTING MEASURES

- | | | |
|--|---|---|
| Suitable extinguishing media | : | Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical |
| Unsuitable extinguishing media | : | None known. |
| Specific hazards during fire fighting | : | Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides Metal oxides |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. |
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SECTION 6. ACCIDENTAL RELEASE MEASURES

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|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment. Follow safe handling advice and personal protective |
|---|---|---|

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- gency procedures
- equipment recommendations.
- Environmental precautions : Discharge into the environment must be avoided.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
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.
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SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Do not get in eyes.
Handle in accordance with good industrial hygiene and safety 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.
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.
Store in accordance with the particular national regulations.
- Materials to avoid : No special restrictions on storage with other products.

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|--------------------|--------------|-------------------------------|--|-----------|
| Sitagliptin | 654671-77-9 | TWA | 0.5 mg/m ³ (OEB 2) | Internal |
| Cellulose | 9004-34-6 | TWA | 10 mg/m ³ | ACGIH |
| | | TWA (Respirable) | 5 mg/m ³ | NIOSH REL |
| | | TWA (total) | 10 mg/m ³ | NIOSH REL |
| | | TWA (total dust) | 15 mg/m ³ | OSHA Z-1 |
| | | TWA (respirable fraction) | 5 mg/m ³ | OSHA Z-1 |
| Ertugliflozin | 1210344-83-4 | TWA | 10 µg/m ³ (OEB 3) | Internal |
| | | Wipe limit | 100 µg/100 cm ² | Internal |
| Magnesium stearate | 557-04-0 | TWA (Inhalable fraction) | 10 mg/m ³ | ACGIH |
| | | TWA (Respirable fraction) | 3 mg/m ³ | ACGIH |

Engineering measures : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
 Minimize open handling.

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material : Chemical-resistant gloves

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- Remarks : Consider double gloving.
- Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.
- Hygiene measures : Ensure that eye flushing systems and safety showers are located close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : powder
- Color : No data available
- Odor : No information available.
- Odor Threshold : No data available
- pH : No data available
- Melting point/freezing point : No data available
- Initial boiling point and boiling range : No data available
- Flash point : Not applicable
- Evaporation rate : Not applicable
- Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
- Flammability (liquids) : No data available

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

SECTION 10. STABILITY AND REACTIVITY

| | | |
|------------------------------------|---|---|
| Reactivity | : | Not classified as a reactivity hazard. |
| Chemical stability | : | Stable under normal conditions. |
| Possibility of hazardous reactions | : | May form explosive dust-air mixture during processing, handling or other means. |
| Conditions to avoid | : | Heat, flames and sparks. Avoid dust formation. |
| Incompatible materials | : | None. |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

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SECTION 11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure**

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:**Sitagliptin:**

Acute oral toxicity : LD50 (Rat): > 3,000 mg/kg
LD50 (Mouse): 3,000 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
Assessment: The substance or mixture has no acute dermal toxicity

Ertugliflozin:

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

Magnesium stearate:

Acute oral toxicity : LD50 (Rat): > 2,500 mg/kg
Assessment: The substance or mixture has no acute oral toxicity

Skin corrosion/irritation

Causes skin irritation.

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Components:

Sitagliptin:

| | |
|---------|----------------------|
| Species | : Rabbit |
| Method | : Draize Test |
| Result | : No skin irritation |

Cellulose:

| | |
|---------|--|
| Result | : No skin irritation |
| Remarks | : Based on data from similar materials |

Ertugliflozin:

| | |
|--------|-------------|
| Result | : Corrosive |
|--------|-------------|

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Sitagliptin:

| | |
|---------|-----------------------|
| Species | : Rabbit |
| Result | : Irritating to eyes. |
| Method | : Draize Test |

Cellulose:

| | |
|---------|--|
| Result | : No eye irritation |
| Remarks | : Based on data from similar materials |

Ertugliflozin:

| | |
|--------|---------------------|
| Result | : Severe irritation |
|--------|---------------------|

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Sitagliptin:

| | |
|-----------|---------------------------------|
| Test Type | : Local lymph node assay (LLNA) |
| Species | : Mouse |
| Method | : OECD Test Guideline 429 |
| Result | : Not a skin sensitizer. |

Cellulose:

| | |
|--------------------|---------------------------------|
| Test Type | : Local lymph node assay (LLNA) |
| Routes of exposure | : Skin contact |

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| | |
|---------|--|
| Species | : Mouse |
| Method | : OECD Test Guideline 429 |
| Result | : negative |
| Remarks | : Based on data from similar materials |

Ertugliflozin:

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

Magnesium stearate:

| | |
|--------------------|----------------|
| Routes of exposure | : Skin contact |
| Result | : negative |

Germ cell mutagenicity

Not classified based on available information.

Components:

Sitagliptin:

| | |
|-----------------------|---|
| Genotoxicity in vitro | : Test Type: Ames test |
| | Result: negative |
| | Test Type: Chromosome aberration test in vitro Test system: Chinese hamster ovary cells Result: negative |
| Genotoxicity in vivo | : Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Test system: rat hepatocytes Result: negative |
| | : Test Type: Micronucleus test |
| | Species: Mouse Application Route: Oral Result: negative |

Cellulose:

| | |
|-----------------------|--|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) |
| | Result: negative |
| | Remarks: Based on data from similar materials |
| Genotoxicity in vivo | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) |
| | Species: Mouse |
| | Application Route: Ingestion |
| | Result: negative |
| | Remarks: Based on data from similar materials |

Ertugliflozin:

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

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| | |
|----------------------|--|
| Genotoxicity in vivo | Result: negative |
| | Test Type: Chromosome aberration test in vitro Result: negative |
| | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Rat Result: negative |

Carcinogenicity

Not classified based on available information.

Components:

Sitagliptin:

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

| | |
|-------------------|--|
| Species | : Rat |
| Application Route | : oral (drinking water) |
| Exposure time | : 2 Years |
| Result | : positive |
| Target Organs | : Liver |
| Remarks | : Significant toxicity observed in testing |

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

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

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

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

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

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Reproductive toxicity

Not classified based on available information.

Components:

Sitagliptin:

Effects on fertility : Test Type: Fertility/early embryonic development
 Species: Rat
 Application Route: Oral
 Fertility: NOAEL Parent: 1,000 mg/kg body weight
 Result: Animal testing did not show any effects on fertility.

Effects on fetal development : Test Type: Embryo-fetal development
 Species: Rat
 Application Route: Oral
 Teratogenicity: LOAEL: 250 mg/kg body weight
 Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects.

Test Type: Embryo-fetal development
 Species: Rabbit
 Teratogenicity: NOAEL: 125 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 fetal development : Test Type: Embryo-fetal development
 Species: Rat
 Application Route: Oral
 Developmental Toxicity: NOAEL: 50 mg/kg body weight
 Remarks: Adverse developmental effects were observed

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

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STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

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

Components:

Ertugliflozin:

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

Repeated dose toxicity

Components:

Sitagliptin:

| | |
|-------------------|---------------|
| Species | : Mouse |
| NOAEL | : 500 mg/kg |
| LOAEL | : 1,000 mg/kg |
| Application Route | : Oral |
| Exposure time | : > 2 y |
| Target Organs | : Kidney |

| | |
|-------------------|-------------------------------|
| Species | : Rat |
| NOAEL | : 500 mg/kg |
| LOAEL | : 1,000 mg/kg |
| Application Route | : Oral |
| Exposure time | : 14 Weeks |
| Target Organs | : Liver, Kidney, Heart, Teeth |

| | |
|-------------------|--|
| Species | : Dog |
| NOAEL | : 10 mg/kg |
| LOAEL | : 50 mg/kg |
| Application Route | : Oral |
| Exposure time | : 53 Weeks |
| Target Organs | : Central nervous system |
| Symptoms | : Loss of balance |
| Remarks | : The mechanism or mode of action may not be relevant in humans. |

| | |
|-------------------|--|
| Species | : Dog |
| NOAEL | : 2 mg/kg |
| LOAEL | : 10 mg/kg |
| Application Route | : Oral |
| Exposure time | : 27 Weeks |
| Target Organs | : Skeletal muscle, Central nervous system |
| Symptoms | : Loss of balance |
| Remarks | : The mechanism or mode of action may not be relevant in humans. |

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Species : Monkey
 NOAEL : 100 mg/kg
 Application Route : Oral
 Exposure time : 14 Weeks
 Remarks : No significant adverse effects were reported

Cellulose:

Species : Rat
 NOAEL : > 5,000 mg/kg
 Application Route : Ingestion
 Exposure time : 90 Days
 Remarks : Based on data from similar materials

Ertugliflozin:

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

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

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

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

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

Species : Mouse
 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

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| | |
|---------------|--|
| Target Organs | : Bone |
| Remarks | : No significant adverse effects were reported |

Magnesium stearate:

| | |
|-------------------|---------------|
| Species | : Rat |
| NOAEL | : 5,000 mg/kg |
| Application Route | : Ingestion |
| Exposure time | : 3 Months |

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Sitagliptin:

| | |
|------------|--|
| Inhalation | : Symptoms: upper respiratory tract infection, pharyngitis, Headache |
| Ingestion | : Symptoms: upper respiratory tract infection, nasopharyngitis, Headache, Nausea, Abdominal pain, Diarrhea |

Ertugliflozin:

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Sitagliptin:

| | |
|---|---|
| Toxicity to fish | : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Daphnia magna (Water flea)): 60 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 |
| Toxicity to algae | : EC50 (Pseudokirchneriella subcapitata (green algae)): > 39 mg/l Exposure time: 96 h Method: OECD Test Guideline 201 |
| | : NOEC (Pseudokirchneriella subcapitata (green algae)): 2.2 mg/l Exposure time: 96 h |

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|--|---|---|
| | | Method: OECD Test Guideline 201 |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Pimephales promelas (fathead minnow)): 9.2 mg/l Exposure time: 33 d Method: OECD Test Guideline 210 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 9.8 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 |
| Toxicity to microorganisms | : | EC50: > 150 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 |
| | | NOEC: 150 mg/l Exposure time: 3 h Test Type: Respiration inhibition |

Cellulose:

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Cyprinus carpio (Carp)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: Based on data from similar materials |
| Toxicity to algae | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials |

Ertugliflozin:

| | | |
|--|---|---|
| Toxicity to algae | : | EC50 (Pseudokirchneriella subcapitata (green algae)): 77 mg/l Method: OECD Test Guideline 201 |
| | | NOEC (Pseudokirchneriella subcapitata (green algae)): 50 mg/l Method: OECD Test Guideline 201 |
| Toxicity to fish (Chronic toxicity) | : | 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 (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 2.14 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 |

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| | | | |
|--|----------------------------|---|--|
| | Toxicity to microorganisms | : | Remarks: No toxicity at the limit of solubility. |
| | | | 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 |

Persistence and degradability

Components:

Sitagliptin:

| | | |
|--------------------|---|--|
| Biodegradability | : | Result: not rapidly degradable Biodegradation: 39.7 % Exposure time: 28 d Method: OECD Test Guideline 314 |
| Stability in water | : | Hydrolysis: 50 % (401 d) Method: OECD Test Guideline 111 |

Cellulose:

| | | |
|------------------|---|--------------------------------|
| Biodegradability | : | Result: Readily biodegradable. |
|------------------|---|--------------------------------|

Ertugliflozin:

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

Magnesium stearate:

| | | |
|------------------|---|----------------------------|
| Biodegradability | : | Result: Not biodegradable. |
|------------------|---|----------------------------|

Bioaccumulative potential

Components:

Sitagliptin:

| | | |
|--|---|----------------|
| Partition coefficient: n-octanol/water | : | log Pow: -0.03 |
|--|---|----------------|

Ertugliflozin:

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

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Mobility in soil**Components:****Ertugliflozin:**

Distribution among environmental compartments : log Koc: 2.88

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

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

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

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Domestic regulation**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION**EPCRA - Emergency Planning and Community Right-to-Know****CERCLA Reportable Quantity**

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

SARA 304 Extremely Hazardous Substances Reportable Quantity

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

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

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

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

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

US State Regulations**Pennsylvania Right To Know**

| | |
|--------------------------------|-------------|
| Sitagliptin | 654671-77-9 |
| Cellulose | 9004-34-6 |
| Calcium hydrogenorthophosphate | 7757-93-9 |
| Sodium octadecyl fumarate | 4070-80-8 |

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

California Permissible Exposure Limits for Chemical Contaminants

| | |
|--------------------|-----------|
| Cellulose | 9004-34-6 |
| Magnesium stearate | 557-04-0 |

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

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

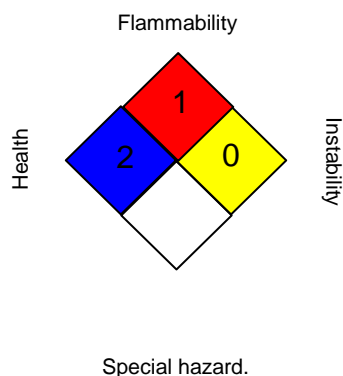
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SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:

| | | |
|------------------------|----------|----------|
| HEALTH | * | 2 |
| FLAMMABILITY | 3 | |
| PHYSICAL HAZARD | 0 | |

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

Full text of other abbreviations

| | | |
|-----------------|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| NIOSH REL | : | USA. NIOSH Recommended Exposure Limits |
| OSHA Z-1 | : | USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants |
| ACGIH / TWA | : | 8-hour, time-weighted average |
| NIOSH REL / TWA | : | Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek |
| OSHA Z-1 / TWA | : | 8-hour time weighted average |

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of

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Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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

Revision Date : 04/12/2018

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

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

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