SAFETY DATA SHEET

Ezetimibe / Simvastatin Formulation

Version 5.7  Revision Date: 16.10.2020  SDS Number: 28133-00016  Date of last issue: 23.03.2020  Date of first issue: 04.11.2014

Section 1: Identification

Product name: Ezetimibe / Simvastatin Formulation

Manufacturer or supplier’s details

Company: Organon & Co.
Address: 30 Hudson Street, 33nd floor  Jersey City, New Jersey, U.S.A 07302
Telephone: 551-430-6000
Emergency telephone number: 215-631-6999
E-mail address: EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical

Section 2: Hazard identification

GHS Classification

Skin corrosion/irritation: Category 2
Skin sensitisation: Category 1
Specific target organ toxicity - repeated exposure: Category 1 (Liver, muscle, optic nerve, Eye)

GHS label elements

Hazard pictograms:

Signal word: Danger
Hazard statements:
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H372 Causes damage to organs (Liver, muscle, optic nerve, Eye) through prolonged or repeated exposure.

Precautionary statements:

Prevention:
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.

Response:
Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
May form explosive dust-air mixture during processing, handling or other means.

Section 3: Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 10 &lt; 30</td>
</tr>
<tr>
<td>Ezetimibe</td>
<td>163222-33-1</td>
<td>&gt;= 10 &lt; 30</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>79902-63-9</td>
<td>&gt;= 10 &lt; 30</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&lt; 10</td>
</tr>
</tbody>
</table>

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.

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.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Causes skin irritation.
May cause an allergic skin reaction.
Causes damage to organs through prolonged or repeated exposure.
Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.
Section 5: Fire-fighting measures

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: 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 (NOx)
Fluorine compounds
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 firefighters: In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Hazchem Code: 2Z

Section 6: Accidental release measures

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

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

Methods and materials for containment and cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
Section 7: Handling and storage

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

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe dust.
- Do not swallow.
- Avoid contact with eyes.
- Wash skin thoroughly after handling.
- 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.
- 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.
- Contaminated work clothing should not be allowed out of the workplace.
- Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage:
- Keep in properly labelled containers.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents

Section 8: Exposure controls/personal protection

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>WES-TWA</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Ezetimibe</td>
<td>163222-33-1</td>
<td>TWA</td>
<td>25 µg/m³ (OEB 3) Internal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>250 µg/100 cm² Internal</td>
<td></td>
</tr>
<tr>
<td>Simvastatin</td>
<td>79902-63-9</td>
<td>TWA</td>
<td>25 µg/m³ (OEB 3) Internal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: DSEN</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>250 µg/100 cm² Internal</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>WES-TWA</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
</tr>
</tbody>
</table>
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: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type
- Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

Eye protection: Wear safety glasses with side shields or goggles.
- If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
- Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection: Work uniform or laboratory coat.
- Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
- Use appropriate degowning techniques to remove potentially contaminated clothing.

Section 9: Physical and chemical properties

Appearance: powder

Colour: No data available

Odour: No data available

Odour Threshold: No data available

pH: No data available

Melting point/freezing point: No data available
## Initial boiling point and boiling range
No data available

## Flash point
No data available

## Evaporation rate
No data available

## Flammability (solid, gas)
May form explosive dust-air mixture during processing, handling or other means.

## Flammability (liquids)
No data available

## Upper explosion limit / Upper flammability limit
No data available

## Lower explosion limit / Lower flammability limit
No data available

## Vapour pressure
No data available

## Relative vapour density
No data available

## Relative density
No data available

## Solubility(ies)

### Water solubility
No data available

## Partition coefficient: n-octanol/water
No data available

## Auto-ignition temperature
No data available

## Decomposition temperature
No data available

## Viscosity

### Viscosity, kinematic
No data available

## Explosive properties
Not explosive

## Oxidizing properties
The substance or mixture is not classified as oxidizing.

## Molecular weight
No data available

## Particle size
No data available

### Section 10: Stability and reactivity

#### Reactivity
Not classified as a reactivity hazard.

#### Chemical stability
Stable under normal conditions.

#### Possibility of hazardous reactions
May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid

Avoid heat, flames and sparks. Avoid dust formation.

Incompatible materials

- Oxidizing agents

Hazardous decomposition products

- No hazardous decomposition products are known.

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Section 11: Toxicological information

Exposure routes

- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity

Not classified based on available information.

**Components:**

**Cellulose:**

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

**Ezetimibe:**

- **Acute oral toxicity**: LD50 (Rat): > 5,000 mg/kg
  - LD50 (Mouse): > 5,000 mg/kg
  - LD50 (Dog): > 3,000 mg/kg
- **Acute inhalation toxicity**: Remarks: No data available
- **Acute dermal toxicity**: Remarks: No data available
- **Acute toxicity (other routes of administration)**:
  - LD50 (Rat): > 2,000 mg/kg
  - Application Route: Intraperitoneal
  - LD50 (Mouse): > 1,000 - < 2,000 mg/kg
  - Application Route: Intraperitoneal

**Simvastatin:**

- **Acute oral toxicity**: LD50 (Rat): 5,000 mg/kg
  - LD50 (Mouse): 3,800 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 toxicity
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Remarks: Based on data from similar materials

Acute dermal toxicity
LD50 (Rabbit): > 2,000 mg/kg
Remarks: Based on data from similar materials

Skin corrosion/irritation
Causes skin irritation.

Components:

Ezetimibe:
Species: Rabbit
Result: No skin irritation

Simvastatin:
Species: Rabbit
Remarks: Moderate skin irritation

Magnesium stearate:
Species: Rabbit
Remarks: Based on data from similar materials

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Ezetimibe:
Species: Rabbit
Result: No eye irritation

Simvastatin:
Species: Rabbit
Remarks: slight irritation

Magnesium stearate:
Species: Rabbit
Remarks: Based on data from similar materials

Respiratory or skin sensitisation

Skin sensitisation
May cause an allergic skin reaction.

Respiratory sensitisation
Not classified based on available information.
Components:

**Ezetimibe:**
- Test Type: Maximisation Test
- Species: Guinea pig
- Result: negative

**Simvastatin:**
- Assessment: Probability or evidence of skin sensitisation in humans
- Result: positive

**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

Chronic toxicity

**Germ cell mutagenicity**
Not classified based on available information.

Components:

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

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

**Ezetimibe:**
- Genotoxicity in vitro:
  - Test Type: Bacterial reverse mutation assay (AMES)
    - Metabolic activation: with and without metabolic activation
      - Result: negative
  - Test Type: Chromosomal aberration
    - Test system: Human lymphocytes
      - Result: negative

- Genotoxicity in vivo:
  - Test Type: Micronucleus test
    - Species: Mouse
    - Cell type: Bone marrow
      - Application Route: Oral
      - Result: negative
**Simvastatin:**

Genotoxicity in vitro:
- **Test Type:** Bacterial reverse mutation assay (AMES)
  - Result: negative
- **Test Type:** Alkaline elution assay
  - Result: negative
- **Test Type:** Chromosomal aberration
  - Result: negative
- **Test Type:** In vitro mammalian cell gene mutation test
  - Result: negative

Genotoxicity in vivo:
- **Test Type:** Micronucleus test
  - **Species:** Mouse
  - **Application Route:** Oral
  - Result: negative

Germ cell mutagenicity - Assessment:
- Weight of evidence does not support classification as a germ cell mutagen.

**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

**Carcinogenicity**

Not classified based on available information.

**Components:**

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

**Ezetimibe:**
- **Species:** Rat, female
- **Application Route:** oral (feed)
- **Exposure time:** 104 weeks
- Result: negative
Species: Rat, male  
Application Route: oral (feed)  
Exposure time: 104 weeks  
Result: negative

Species: Mouse  
Application Route: oral (feed)  
Exposure time: 104 weeks  
Result: negative

Simvastatin:
Species: Mouse  
Application Route: Oral  
Exposure time: < 92 weeks  
Target Organs: Harderian gland  
Tumor Type: Liver, Lungs  
Remarks: The significance of these findings for humans is not certain.

Species: Rat  
Application Route: Oral  
Exposure time: 2 Years  
Tumor Type: Liver, Thyroid  
Remarks: The significance of these findings for humans is not certain.

Reproductive toxicity  
Not classified based on available information.

Components:

Cellulose:
Effects on fertility: Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on foetal development: Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative

Ezetimibe:
Effects on fertility: Test Type: Fertility/early embryonic development  
Species: Rat, male and female  
Fertility: NOAEL: > 1,000 mg/kg body weight  
Result: No effects on fertility, No fetotoxicity

Effects on foetal development: Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: > 1,000 mg/kg body weight  
Result: No adverse effects
Test Type: Development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: NOAEL: > 1,000 mg/kg body weight  
Result: No adverse effects

Simvastatin:

Effects on fertility:  
Test Type: Fertility  
Species: Rat, male  
Application Route: Oral  
Fertility: LOAEL: 25 mg/kg body weight  
Result: No adverse effects

Effects on foetal development:  
Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Embryo-foetal toxicity: NOAEL: 25 mg/kg body weight  
Result: No teratogenic effects, No adverse effects

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Oral  
Embryo-foetal toxicity: NOAEL: 10 mg/kg body weight  
Result: No teratogenic effects, No adverse effects

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Embryo-foetal toxicity: LOAEL: 60 mg/kg body weight  
Result: Teratogenic potential  
Remarks: Based on data from similar materials

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 development:  
Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Causes damage to organs (Liver, muscle, optic nerve, Eye) through prolonged or repeated exposure.
## Components:

### Simvastatin:
- **Target Organs**: Liver, muscle, optic nerve, Eye
- **Assessment**: Causes damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

#### Components:

#### Cellulose:
- **Species**: Rat
- **NOAEL**: \( \geq 9,000 \) mg/kg
- **Application Route**: Ingestion
- **Exposure time**: 90 Days

#### Ezetimibe:
- **Species**: Dog
- **NOAEL**: 1,000 mg/kg
- **Application Route**: Oral
- **Exposure time**: 90 d
- **Remarks**: No significant adverse effects were reported

- **Species**: Rat
- **NOAEL**: 1,500 mg/kg
- **Application Route**: Oral
- **Exposure time**: 90 d
- **Remarks**: No significant adverse effects were reported

- **Species**: Mouse
- **NOAEL**: 500 mg/kg
- **Application Route**: Oral
- **Exposure time**: 90 d
- **Remarks**: No significant adverse effects were reported

- **Species**: Dog
- **NOAEL**: 300 mg/kg
- **Application Route**: Oral
- **Exposure time**: 1 yr
- **Remarks**: No significant adverse effects were reported

#### Simvastatin:
- **Species**: Rat
- **NOAEL**: 5 mg/kg
- **LOAEL**: 30 mg/kg
- **Application Route**: Oral
- **Exposure time**: 14 - 104 Weeks
- **Target Organs**: Liver, Testis, Musculo-skeletal system, Eye

- **Species**: Dog
- **LOAEL**: 10 mg/kg
- **Application Route**: Oral
Exposure time: 14 - 104 Weeks
Target Organs: Liver, Testis, Eye

Species: Rabbit
NOAEL: 30 mg/kg
LOAEL: 50 mg/kg
Application Route: Oral
Target Organs: Liver, Kidney

Magnesium stearate:
Species: Rat
NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Remarks: Based on data from similar materials

Aspiration toxicity
Not classified based on available information.

Components:
Ezetimibe:
Not applicable

Experience with human exposure

Components:
Ezetimibe:
Ingestion: Symptoms: Headache, Nausea, Vomiting, Diarrhoea, flatulence, muscle pain, upper respiratory tract infection, Back pain, joint pain
Simvastatin:
Skin contact: Remarks: May produce an allergic reaction.
Ingestion: Target Organs: Liver
Symptoms: upper respiratory tract infection, Headache, Abdominal pain, constipation, Nausea
Target Organs: Musculo-skeletal system

Section 12: Ecological information

Ecotoxicity

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

Ezetimibe:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 0.125 mg/l
**SAFETY DATA SHEET**

**Ezetimibe / Simvastatin Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue: 23.03.2020</th>
<th>Date of first issue: 04.11.2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.7</td>
<td>16.10.2020</td>
<td>28133-00016</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to daphnia and other aquatic invertebrates

- EC50 (Daphnia magna (Water flea)): > 4 mg/l
- Exposure time: 48 h
- Method: OECD Test Guideline 202
- Remarks: No toxicity at the limit of solubility

### Toxicity to algae/aquatic plants

- EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.317 mg/l
- Exposure time: 96 h
- Method: OECD Test Guideline 201
- Remarks: No toxicity at the limit of solubility

- NOEC (Pseudokirchneriella subcapitata (green algae)): 0.317 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 201
  - Remarks: No toxicity at the limit of solubility

### Toxicity to fish (Chronic toxicity)

- NOEC (Pimephales promelas (fathead minnow)): 0.051 mg/l
  - Exposure time: 33 d
  - Method: OECD Test Guideline 210

- NOEC (Cyprinodon variegatus (sheepshead minnow)): 4 mg/l
  - Exposure time: 7 d
  - Method: OECD Test Guideline 201
  - Remarks: No toxicity at the limit of solubility

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

- NOEC (Daphnia magna (Water flea)): 0.282 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 201
  - Remarks: No toxicity at the limit of solubility

### Toxicity to microorganisms

- EC50: > 4.4 mg/l
  - Exposure time: 3 h
  - Method: OECD Test Guideline 209
  - remarks: No toxicity at the limit of solubility

- NOEC: 4.4 mg/l
  - Exposure time: 3 h
  - Method: OECD Test Guideline 209
  - Remarks: No toxicity at the limit of solubility

### Simvastatin

#### Toxicity to fish

- LC50 (Pimephales promelas (fathead minnow)): 2.91 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203

#### Toxicity to daphnia and other aquatic invertebrates

- EC50 (Daphnia magna (Water flea)): 3.5 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae))</th>
<th>NOEC (Pseudokirchneriella subcapitata (green algae))</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt; 25 mg/l</td>
<td>25 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
<td>Exposure time: 96 h</td>
</tr>
</tbody>
</table>

Exposure time: 96 h

Toxicity to microorganisms:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>EC50: &gt; 30 mg/l</th>
<th>NOEC: 21 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td></td>
<td>Test Type: Respiration inhibition</td>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 209</td>
<td>Method: OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

Exposure time: 3 h

Magnesium stearate:

Toxicity to fish:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>LC50 (Leuciscus idus (Golden orfe))</th>
<th>Method: DIN 38412</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt; 100 mg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
<td></td>
</tr>
</tbody>
</table>

Exposure time: 48 h

Toxicity to daphnia and other aquatic invertebrates:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>EL50 (Daphnia magna (Water flea))</th>
<th>Test substance: Water Accommodated Fraction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 47 h</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

Exposure time: 47 h

Toxicity to algae/aquatic plants:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>EL50 (Pseudokirchneriella subcapitata (green algae))</th>
<th>NOELR (Pseudokirchneriella subcapitata (green algae))</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt; 1 mg/l</td>
<td>&gt; 1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

Exposure time: 72 h

Toxicity to microorganisms:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>EC10 (Pseudomonas putida)</th>
<th>Test substance: Water Accommodated Fraction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt; 100 mg/l</td>
<td>Method: OECD Test Guideline 201</td>
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<tr>
<td></td>
<td>Exposure time: 16 h</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

Exposure time: 16 h
Persistence and degradability

**Components:**

**Cellulose:**
Biodegradability : Result: Readily biodegradable.

**Ezetimibe:**
Biodegradability : Result: Not readily biodegradable.
   Biodegradation: 6.8 %
   Exposure time: 28 d
Stability in water : Hydrolysis: 50 %(4.5 d)
   Method: OECD Test Guideline 111

**Simvastatin:**
Biodegradability : Result: rapidly degradable
Stability in water : Hydrolysis: 50 %(3.2 d)

**Magnesium stearate:**
Biodegradability : Result: Not biodegradable
   Remarks: Based on data from similar materials

Bioaccumulative potential

**Components:**

**Ezetimibe:**
Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
   Bioconcentration factor (BCF): 173
   Exposure time: 97 d
   Method: OECD Test Guideline 305
   Partition coefficient: n-octanol/water : log Pow: 4.36

**Simvastatin:**
Partition coefficient: n-octanol/water : log Pow: > 4.07

**Magnesium stearate:**
Partition coefficient: n-octanol/water : log Pow: > 4

Mobility in soil

**Components:**

**Ezetimibe:**
Distribution among environmental compartments : log Koc: 4.35
   Method: OECD Test Guideline 106
## 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

<table>
<thead>
<tr>
<th>UNRTDG</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UN number</strong></td>
</tr>
<tr>
<td><strong>Proper shipping name</strong></td>
</tr>
<tr>
<td><strong>Class</strong></td>
</tr>
<tr>
<td><strong>Packing group</strong></td>
</tr>
<tr>
<td><strong>Labels</strong></td>
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</table>

<table>
<thead>
<tr>
<th>IATA-DGR</th>
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<tbody>
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<tr>
<td><strong>Packing group</strong></td>
</tr>
<tr>
<td><strong>Labels</strong></td>
</tr>
<tr>
<td><strong>Packing instruction (cargo aircraft)</strong></td>
</tr>
<tr>
<td><strong>Packing instruction (passenger aircraft)</strong></td>
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<tr>
<td><strong>Environmentally hazardous</strong></td>
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</table>

<table>
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<tr>
<th>IMDG-Code</th>
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</thead>
<tbody>
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<td><strong>Proper shipping name</strong></td>
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<td><strong>Packing group</strong></td>
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<tr>
<td><strong>EmS Code</strong></td>
</tr>
<tr>
<td><strong>Marine pollutant</strong></td>
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</tbody>
</table>

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
Not applicable for product as supplied.

#### National Regulations

<table>
<thead>
<tr>
<th>NZS 5433</th>
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<tbody>
<tr>
<td><strong>UN number</strong></td>
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<tr>
<td><strong>Proper shipping name</strong></td>
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</tbody>
</table>
Section 15: Regulatory information

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

HSNO Approval Number
HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

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

Section 16: Other information

Further information

Date format : dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average
SAFETY DATA SHEET

Ezetimibe / Simvastatin Formulation

Version 5.7
Revision Date: 16.10.2020
SDS Number: 28133-00016
Date of last issue: 23.03.2020
Date of first issue: 04.11.2014

Modified to include new data.

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; 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.

NZ / EN