1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ezetimibe / Simvastatin Formulation

Manufacturer or supplier’s details
Company : MSD
Address : JL Raya Pandaan KM. 48
           Pandaan, Jawa Timur - Indonesia
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

2. HAZARDS 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)
Long-term (chronic) aquatic hazard : Category 2

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.
                   H411 Toxic to aquatic life with long lasting effects.
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.
P273 Avoid release to the environment.
P280 Wear protective gloves.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
P314 Get medical advice/ attention if you feel unwell.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

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

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Cellulose</td>
</tr>
<tr>
<td></td>
<td>Ezetimibe</td>
</tr>
<tr>
<td></td>
<td>Simvastatin</td>
</tr>
<tr>
<td></td>
<td>Magnesium stearate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>≥ 10 &lt; 30</td>
</tr>
<tr>
<td>Ezetimibe</td>
<td>163222-33-1</td>
<td>≥ 10 &lt; 25</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>79902-63-9</td>
<td>≥ 10 &lt; 25</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&lt; 10</td>
</tr>
</tbody>
</table>

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.

## 5. FIREFIGHTING MEASURES

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol-resistant foam</td>
<td></td>
</tr>
<tr>
<td>Carbon dioxide (CO2)</td>
<td></td>
</tr>
<tr>
<td>Dry chemical</td>
<td></td>
</tr>
</tbody>
</table>

| 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. |

<table>
<thead>
<tr>
<th>Hazardous combustion products</th>
<th>Carbon oxides</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitrogen oxides (NOx)</td>
<td></td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td></td>
</tr>
<tr>
<td>Metal oxides</td>
<td></td>
</tr>
</tbody>
</table>

| 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. |

## 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 re- |
leased 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.

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.

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

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<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>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)</td>
<td>Internal</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>79902-63-9</td>
<td>TWA</td>
<td>25 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>NAB</td>
<td>10 mg/m³</td>
<td>ID OEL</td>
</tr>
</tbody>
</table>

Further information: DSEN

Wipe limit: 250 µg/100 cm² Internal

Further information: Adopted in Year 1996, Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals

TWA (Inhal): 10 mg/m³ ACGIH
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
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: Heat, flames and sparks. Avoid dust formation.

Incompatible materials: Oxidizing agents

Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- 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
# 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:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.7</td>
<td>2020/10/16</td>
<td>28120-00016</td>
<td>2020/03/23</td>
<td>2014/11/04</td>
</tr>
</tbody>
</table>

### 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
  - 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
- **Result**: No skin irritation
- **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
- **Result**: No eye irritation
- **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

Germ cell mutagenicity
Not classified based on available information.

Components:

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

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

Ezetimibe:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Metabolic activation: with and without metabolic activation
Result: negative

Genotoxicity in vivo: Test Type: Chromosomal aberration
Test system: Human lymphocytes

SDS Number: 28120-00016
Date of last issue: 2020/03/23
Date of first issue: 2014/11/04
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

**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**: $\geq 9,000 \text{ mg/kg}$
- **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:
- **Species**: Rat
- **NOAEL**: 1,500 mg/kg
- **Application Route**: Oral
- **Exposure time**: 90 d
- **Remarks**: No significant adverse effects were reported

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

Species:
- **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  
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
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: No toxicity at the limit of solubility

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
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
Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic toxicity) : 1

Toxicity to microorganisms : EC50: > 4.4 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

NOEC: 4.4 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
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
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Substance</th>
<th>EC50 (mg/l)</th>
<th>Exposure Time (h)</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea))</td>
<td>3.5</td>
<td>48</td>
<td>OECD Test Guideline 202</td>
</tr>
<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae))</td>
<td>25</td>
<td>96</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOELR (Pseudokirchneriella subcapitata (green algae))</td>
<td>&gt; 1</td>
<td>72</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOELR (Pseudomonas putida)</td>
<td>&gt; 100</td>
<td>24</td>
<td></td>
</tr>
</tbody>
</table>

Magnesium stearate:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Substance</th>
<th>EC50 (mg/l)</th>
<th>Exposure Time (h)</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Leuciscus idus (Golden orfe))</td>
<td>&gt; 100</td>
<td>48</td>
<td>DIN 38412</td>
</tr>
<tr>
<td></td>
<td>Remarks</td>
<td></td>
<td></td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EL50 (Daphnia magna (Water flea))</td>
<td>&gt; 1</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>Remarks</td>
<td></td>
<td></td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No toxicity at the limit of solubility</td>
</tr>
<tr>
<td></td>
<td>Toxicity to algae/aquatic plants</td>
<td>EL50 (Pseudokirchneriella subcapitata (green algae))</td>
<td>&gt; 1</td>
<td>OECD Test Guideline 201</td>
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<td>NOELR (Pseudokirchneriella subcapitata (green algae))</td>
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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

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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe, Simvastatin)
Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Ezetimibe, Simvastatin)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 956
Packing instruction (passenger aircraft): 956
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe, Simvastatin)
Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

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

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

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information
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.