SAFETY DATA SHEET

Ezetimibe Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ezetimibe Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil  13106-054
Telephone : 908-740-4000
Emergency telephone : 55 19 3758 2000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Skin irritation : Category 3
Long-term (chronic) aquatic hazard : Category 2

GHS label elements in accordance with ABNT NBR 14725 Standard
Hazard pictograms :

Signal Word : Warning
Hazard Statements : H316 Causes mild skin irritation.
H411 Toxic to aquatic life with long lasting effects.

Precautionary Statements :
Prevention:
P273 Avoid release to the environment.
Response:
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P391 Collect spillage.
SAFETY DATA SHEET

Ezetimibe Formulation

Version 3.0  Revision Date: 09/13/2019  SDS Number: 23819-00013  Date of last issue: 24.04.2019  Date of first issue: 21.10.2014

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

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td></td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Ezetimibe</td>
<td>163222-33-1</td>
<td>Long-term (chronic) aquatic hazard, Category 1</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
<td>Acute toxicity (Oral), Category 4, Skin irritation, Category 2, Serious eye damage, Category 1, Short-term (acute) aquatic hazard, Category 2, Long-term (chronic) aquatic hazard, Category 3</td>
<td>&gt;= 1 - &lt; 2,5</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td></td>
<td>&gt;= 1 - &lt; 5</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. Remove 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 mild skin irritation. 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.
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
- Sulfur 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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

- Use personal protective equipment.
- Follow safe handling advice and personal protective 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 spills 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. 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.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage : Keep in properly labeled 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

Ingredients 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>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable fraction)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>3 mg/m³</td>
<td>ACGIH</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: Particulates 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
- Color: off-white
- Odor: No data 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: No data available
- Flammability (solid, gas): May form explosive dust-air mixture during processing,
handle 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

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies) : No data available

Water solubility : No data available

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

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity : No data available

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 : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

**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:

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

Sodium n-dodecyl sulfate:
Acute oral toxicity: LD50 (Rat): 1.200 mg/kg
   Method: OECD Test Guideline 401
Acute dermal toxicity: LD50 (Rat): > 2.000 mg/kg
   Method: OECD Test Guideline 402
   Remarks: Based on data from similar materials

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 mild skin irritation.

Components:

Ezetimibe:
Species: Rabbit
Result: No skin irritation

Sodium n-dodecyl sulfate:
Species: Rabbit
Result: 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

Sodium n-dodecyl sulfate:
Species: Rabbit
Result: Irreversible effects on the eye
Method: OECD Test Guideline 405

Magnesium stearate:
Species: Rabbit
Result: No eye irritation
Remarks: Based on data from similar materials

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.
Components:

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

**Sodium n-dodecyl sulfate:**
- **Test Type**: Maximization Test
- **Routes of exposure**: Skin contact
- **Species**: Guinea pig
- **Result**: negative
- **Remarks**: Based on data from similar materials

**Magnesium stearate:**
- **Test Type**: Maximization Test
- **Routes of exposure**: 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
  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

**Sodium n-dodecyl sulfate:**

Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
- Method: OECD Test Guideline 471
- Result: negative
- Test Type: In vitro mammalian cell gene mutation test
- Result: negative

Genotoxicity in vivo:
- Test Type: Rodent dominant lethal test (germ cell) (in vivo)
- Species: Mouse
- Application Route: Ingestion
- Result: negative

**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

**Sodium n-dodecyl sulfate:**
Species: Rat  
Application Route: Ingestion  
Exposure time: 2 Years  
Method: OECD Test Guideline 453  
Result: negative  
Remarks: Based on data from similar materials

**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 fetal 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 fetal 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.

**Sodium n-dodecyl sulfate:**
Effects on fertility: Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 416
Result: negative  
Remarks: Based on data from similar materials

**Effects on fetal development**:
- **Test Type**: Embryo-fetal development  
- **Species**: Rat  
- **Application Route**: Ingestion  
- **Result**: negative  
- **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 fetal development**:
  - **Test Type**: Embryo-fetal 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**
Not classified based on available information.

**Repeated dose toxicity**

**Components**:

**Cellulose**:
- **Species**: Rat  
- **NOAEL**: >= 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

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>1.500 mg/kg</td>
<td>Oral</td>
<td>90 d</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

**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 y  
Remarks: No significant adverse effects were reported

Sodium n-dodecyl sulfate:  
Species: Rat  
NOAEL: 488 mg/kg  
Application Route: Ingestion  
Exposure time: 90 Days  
Remarks: Based on data from similar materials

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, Diarrhea, flatulence, muscle pain, upper respiratory tract infection, Back pain, joint pain

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 Formulation

<table>
<thead>
<tr>
<th>Ezetimibe:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
</tr>
<tr>
<td><em>LC50 (Pimephales promelas (fathead minnow)):</em></td>
</tr>
<tr>
<td>&gt; 0.125 mg/l</td>
</tr>
<tr>
<td><em>Exposure time:</em></td>
</tr>
<tr>
<td>96 h</td>
</tr>
<tr>
<td><em>Method:</em></td>
</tr>
<tr>
<td>OECD Test Guideline 203</td>
</tr>
<tr>
<td><em>Remarks:</em></td>
</tr>
<tr>
<td>No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
</tr>
<tr>
<td><em>EC50 (Daphnia magna (Water flea)):</em></td>
</tr>
<tr>
<td>&gt; 4 mg/l</td>
</tr>
<tr>
<td><em>Exposure time:</em></td>
</tr>
<tr>
<td>48 h</td>
</tr>
<tr>
<td><em>Method:</em></td>
</tr>
<tr>
<td>OECD Test Guideline 202</td>
</tr>
<tr>
<td><em>Remarks:</em></td>
</tr>
<tr>
<td>No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
</tr>
<tr>
<td><em>EC50 (Pseudokirchneriella subcapitata (green algae)):</em></td>
</tr>
<tr>
<td>&gt; 0.317 mg/l</td>
</tr>
<tr>
<td><em>Exposure time:</em></td>
</tr>
<tr>
<td>96 h</td>
</tr>
<tr>
<td><em>Method:</em></td>
</tr>
<tr>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td><em>Remarks:</em></td>
</tr>
<tr>
<td>No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td><strong>NOEC (Pseudokirchneriella subcapitata (green algae)):</strong>*</td>
</tr>
<tr>
<td>0,317 mg/l</td>
</tr>
<tr>
<td><em>Exposure time:</em></td>
</tr>
<tr>
<td>96 h</td>
</tr>
<tr>
<td><em>Method:</em></td>
</tr>
<tr>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td><em>Remarks:</em></td>
</tr>
<tr>
<td>No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td><strong>Toxicity to fish (Chronic toxicity)</strong></td>
</tr>
<tr>
<td><em>NOEC (Pimephales promelas (fathead minnow)):</em></td>
</tr>
<tr>
<td>0.051 mg/l</td>
</tr>
<tr>
<td><em>Exposure time:</em></td>
</tr>
<tr>
<td>33 d</td>
</tr>
<tr>
<td><em>Method:</em></td>
</tr>
<tr>
<td>OECD Test Guideline 210</td>
</tr>
<tr>
<td><strong>NOEC (Cyprinodon variegatus (sheepshead minnow)):</strong>*</td>
</tr>
<tr>
<td>4 mg/l</td>
</tr>
<tr>
<td><em>Exposure time:</em></td>
</tr>
<tr>
<td>7 d</td>
</tr>
<tr>
<td><em>Remarks:</em></td>
</tr>
<tr>
<td>No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></td>
</tr>
<tr>
<td><em>NOEC (Daphnia magna (Water flea)):</em></td>
</tr>
<tr>
<td>0.282 mg/l</td>
</tr>
<tr>
<td><em>Exposure time:</em></td>
</tr>
<tr>
<td>21 d</td>
</tr>
<tr>
<td><em>Remarks:</em></td>
</tr>
<tr>
<td>No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td><strong>M-Factor (Chronic aquatic toxicity)</strong></td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td><strong>Toxicity to microorganisms</strong></td>
</tr>
<tr>
<td><em>EC50: &gt; 4,4 mg/l</em></td>
</tr>
<tr>
<td><em>Exposure time:</em></td>
</tr>
<tr>
<td>3 h</td>
</tr>
<tr>
<td><em>Test Type:</em></td>
</tr>
<tr>
<td>Respiration inhibition</td>
</tr>
<tr>
<td><em>Method:</em></td>
</tr>
<tr>
<td>OECD Test Guideline 209</td>
</tr>
<tr>
<td><em>Remarks:</em></td>
</tr>
<tr>
<td>No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td><strong>NOEC: 4.4 mg/l</strong></td>
</tr>
<tr>
<td><em>Exposure time:</em></td>
</tr>
<tr>
<td>3 h</td>
</tr>
<tr>
<td><em>Test Type:</em></td>
</tr>
<tr>
<td>Respiration inhibition</td>
</tr>
<tr>
<td><em>Method:</em></td>
</tr>
<tr>
<td>OECD Test Guideline 209</td>
</tr>
<tr>
<td><em>Remarks:</em></td>
</tr>
<tr>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

**Sodium n-dodecyl sulfate:**

| **Toxicity to fish**                                 |
| *LC50 (Pimephales promelas (fathead minnow)):*       |
| 29 mg/l                                              |
| *Exposure time:*                                     |
| 96 h                                                 |

| **Toxicity to daphnia and other**                    |
| *EC50 (Ceriodaphnia dubia (water flea)):*            |
| 5.55 mg/l                                            |
### Aquatic Invertebrates
Exposure time: 48 h

#### Toxicity to Algae/Aquatic Plants
- **ErC50** (Desmodesmus subspicatus (green algae)): > 120 mg/l  
  Exposure time: 72 h
- **NOEC** (Desmodesmus subspicatus (green algae)): 30 mg/l  
  Exposure time: 72 h

#### Toxicity to Fish (Chronic Toxicity)
- **NOEC** (Pimephales promelas (fathead minnow)): >= 1,357 mg/l  
  Exposure time: 42 d

#### Toxicity to Daphnia and Other Aquatic Invertebrates (Chronic Toxicity)
- **NOEC** (Ceriodaphnia dubia (water flea)): 0.88 mg/l  
  Exposure time: 7 d

#### Toxicity to Microorganisms
- **EC50**: 135 mg/l  
  Exposure time: 3 h

### Magnesium Stearate

#### Toxicity to Fish
- **LC50** (Leuciscus idus (Golden orfe)): > 100 mg/l  
  Exposure time: 48 h  
  Method: DIN 38412  
  Remarks: Based on data from similar materials

#### Toxicity to Daphnia and Other Aquatic Invertebrates
- **EL50** (Daphnia magna (Water flea)): > 1 mg/l  
  Exposure time: 47 h  
  Test substance: Water Accommodated Fraction  
  Remarks: Based on data from similar materials  
  No toxicity at the limit of solubility.

#### Toxicity to Algae/Aquatic Plants
- **EL50** (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
  Exposure time: 72 h  
  Test substance: Water Accommodated Fraction  
  Method: OECD Test Guideline 201  
  Remarks: Based on data from similar materials  
  No toxicity at the limit of solubility.

- **NOELR** (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
  Exposure time: 72 h  
  Test substance: Water Accommodated Fraction  
  Method: OECD Test Guideline 201  
  Remarks: Based on data from similar materials

#### Toxicity to Microorganisms
- **EC10** (Pseudomonas putida): > 100 mg/l  
  Exposure time: 16 h  
  Test substance: Water Accommodated Fraction  
  Remarks: Based on data from similar materials
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

**Sodium n-dodecyl sulfate:**
- Biodegradability: Result: Readily biodegradable.  
  Biodegradation: 95 %  
  Exposure time: 28 d  
  Method: OECD Test Guideline 301B

**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

**Sodium n-dodecyl sulfate:**
- Partition coefficient: n-octanol/water: log Pow: 0.83

**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
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
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe)
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)
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)
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.

Domestic regulation

ANTT
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
SAFETY DATA SHEET

Ezetimibe Formulation

Version 3.0  Revision Date: 09/13/2019  SDS Number: 23819-00013  Date of last issue: 24.04.2019

N.O.S. (Ezetimibe)

Class : 9
Packing group : III
Labels : 9
Hazard Identification Number : 90

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.

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. Ordinance No. 1274 on the control and monitoring of chemicals. : Not applicable

International Regulations

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information


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

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

AICS - Australian Inventory of Chemical Substances; 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
SAFETY DATA SHEET

Ezetimibe Formulation

Version 3.0  Revision Date: 09/13/2019  SDS Number: 23819-00013  Date of last issue: 24.04.2019  Date of first issue: 21.10.2014

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.

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