SAFETY DATA SHEET

Ezetimibe Granules 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>3.0</td>
<td>09/13/2019</td>
<td>1563965-00006</td>
<td>2019/04/24</td>
<td>2017/04/18</td>
</tr>
</tbody>
</table>

1. PRODUCT AND COMPANY IDENTIFICATION

**Product name** : Ezetimibe Granules 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**
- **Long-term (chronic) aquatic hazard** : Category 2

**GHS label elements**
- **Hazard pictograms** :
- **Signal word** : None
- **Hazard statements** : H411 Toxic to aquatic life with long lasting effects.

**Precautionary statements**
- **Prevention**:
  - P273 Avoid release to the environment.
- **Response**:
  - 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>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 10 -&lt; 30</td>
</tr>
<tr>
<td></td>
<td>Ezetimibe</td>
<td>163222-33-1</td>
<td>&gt;= 2.5 -&lt; 10</td>
</tr>
<tr>
<td></td>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
<td>&gt;= 1 -&lt; 2.5</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. 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: 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

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
- Sulphur 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 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 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 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.

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 advice on safe handling:
- Use only with adequate ventilation.
- 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.
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Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly 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></td>
<td></td>
<td>Wipe limit</td>
<td>250 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures:
- Ensure adequate ventilation, especially in confined areas.
- Minimize workplace exposure concentrations.
- Apply measures to prevent dust explosions.
- Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

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
- Material: Chemical-resistant gloves

Remarks:
- Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection:
- Wear the following personal protective equipment:
  - Safety goggles

Skin and body protection:
- Skin should be washed after contact.

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.
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td>granular</td>
</tr>
<tr>
<td><strong>Colour</strong></td>
<td>white</td>
</tr>
<tr>
<td><strong>Odour</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Odour Threshold</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Melting point/freezing point</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Initial boiling point and boiling range</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flammability (solid, gas)</strong></td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td><strong>Flammability (liquids)</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Upper explosion limit / Upper flammability limit</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Lower explosion limit / Lower flammability limit</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Vapour pressure</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Relative vapour density</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Density</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Solubility(ies)</strong></td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Partition coefficient: n-octanol/water</strong></td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Decomposition temperature</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Viscosity</strong></td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Explosive properties</strong></td>
<td>Not explosive</td>
</tr>
<tr>
<td><strong>Oxidizing properties</strong></td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td><strong>Molecular weight</strong></td>
<td>No data available</td>
</tr>
</tbody>
</table>
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.

Product:
Acute oral toxicity: Acute toxicity estimate: > 2,000 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): LD50 (Rat): > 2,000 mg/kg
**Safety Data Sheet**

**Ezetimibe Granules Formulation**

**Version**: 3.0  
**Revision Date**: 09/13/2019  
**SDS Number**: 1563965-00006  
**Date of last issue**: 2019/04/24  
**Date of first issue**: 2017/04/18

<table>
<thead>
<tr>
<th>Administration)</th>
<th>Application Route: Intraperitoneal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LD50 (Mouse): &gt; 1,000 - &lt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intraperitoneal</td>
</tr>
</tbody>
</table>

**Sodium n-dodecyl sulfate:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): 1,200 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Method: OECD Test Guideline 401</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acute dermal toxicity</th>
<th>LD50 (Rat): &gt; 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Method: OECD Test Guideline 402</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**Ezetimibe:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

**Sodium n-dodecyl sulfate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Skin irritation</td>
</tr>
</tbody>
</table>

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**Ezetimibe:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

**Sodium n-dodecyl sulfate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Irreversible effects on the eye</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 405</td>
</tr>
</tbody>
</table>

**Respiratory or skin sensitisation**

**Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:**

**Ezetimibe:**

| Test Type | Maximisation Test |
Species : Guinea pig
Result : negative

**Sodium n-dodecyl sulfate:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximisation Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Germ cell mutagenicity**

*Not classified based on available information.*

**Components:**

**Cellulose:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES) Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: In vitro mammalian cell gene mutation test Result: negative</td>
</tr>
<tr>
<td>Genotoxicity in vivo</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
</tr>
<tr>
<td></td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

**Ezetimibe:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES) Metabolic activation: with and without metabolic activation Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: Chromosomal aberration</td>
</tr>
<tr>
<td></td>
<td>Test system: Human lymphocytes</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td>Genotoxicity in vivo</td>
<td>Test Type: Micronucleus test</td>
</tr>
<tr>
<td></td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Cell type: Bone marrow</td>
</tr>
<tr>
<td></td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

**Sodium n-dodecyl sulfate:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: In vitro mammalian cell gene mutation test Result: negative</td>
</tr>
<tr>
<td>Genotoxicity in vivo</td>
<td>Test Type: Rodent dominant lethal test (germ cell) (in vivo)</td>
</tr>
</tbody>
</table>
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 foetal development: Test Type: Fertility/early embryonic development
  Species: Rat
  Application Route: Ingestion
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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

**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 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**
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

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

Sodium n-dodecyl sulfate:
Species: Rat
NOAEL: 488 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

12. ECOLOGICAL INFORMATION

Ecotoxicity
Components:

Cellulose:
## Toxicity to fish

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50 (Orzias latipes (Japanese medaka)):</th>
<th>Exposure time: 48 h</th>
<th>Remarks: Based on data from similar materials</th>
</tr>
</thead>
</table>

### Ezetimibe:

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Pimephales promelas (fathead minnow)):</th>
<th>Exposure time: 96 h</th>
<th>Remarks: No toxicity at the limit of solubility</th>
</tr>
</thead>
</table>

### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Daphnia magna (Water flea)):</th>
<th>Exposure time: 48 h</th>
<th>Remarks: No toxicity at the limit of solubility</th>
</tr>
</thead>
</table>

### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)):</th>
<th>Exposure time: 96 h</th>
<th>Remarks: No toxicity at the limit of solubility</th>
</tr>
</thead>
</table>

### Toxicity to fish (Chronic toxicity)

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC (Pimephales promelas (fathead minnow)):</th>
<th>Exposure time: 33 d</th>
<th>Remarks: No toxicity at the limit of solubility</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC (Daphnia magna (Water flea)):</th>
<th>Exposure time: 7 d</th>
<th>Remarks: No toxicity at the limit of solubility</th>
</tr>
</thead>
</table>

### M-Factor (Chronic aquatic toxicity)

| Substance                               | 1                                      |

### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50: &gt; 4.4 mg/l</th>
<th>Exposure time: 3 h</th>
<th>Test Type: Respiration inhibition</th>
<th>Method: OECD Test Guideline 209</th>
<th>Remarks: No toxicity at the limit of solubility</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC: 4.4 mg/l</th>
<th>Exposure time: 3 h</th>
<th>Test Type: Respiration inhibition</th>
<th>Method: OECD Test Guideline 209</th>
<th>Remarks: No toxicity at the limit of solubility</th>
</tr>
</thead>
</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 aquatic invertebrates: EC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l
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

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

Bioaccumulative potential

Components:

Ezetimibe:
Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 173
Exposure time: 97 d
Method: OECD Test Guideline 305
SAFETY DATA SHEET

Ezetimibe Granules Formulation

Partition coefficient: n-octanol/water: log Pow: 4.36

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

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)
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,
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

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

Date format: yyyy/mm/dd

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 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 Chemicals 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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