1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ezetimibe Formulation

Manufacturer or supplier’s details

Company : MSD
Address : 199 Wenhai North Road
          HEDA, Hangzhou - Zhejiang Province - CHINA 310018
Telephone : 908-740-4000
Emergency telephone number : 86-571-87268110
E-mail address : EHSDATASTeward@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance : powder
Colour : off-white
Odour : No data available

Causes mild skin irritation. Toxic to aquatic life with long lasting effects.

GHS Classification

Skin corrosion/irritation : Category 3
Long-term (chronic) aquatic hazard : Category 2

GHS label elements

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/ atten-
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Ezetimibe Formulation

Version 3.0  Revision Date: 09/13/2019  SDS Number: 23826-00013  Date of last issue: 2019/04/24
Date of first issue: 2014/10/21

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

Physical and chemical hazards
Not classified based on available information.

Health hazards
Causes mild skin irritation.

Environmental hazards
Toxic to aquatic life with long lasting effects.

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>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Ezetimibe</td>
<td>163222-33-1</td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</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
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 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

Handling
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.
Avoidance of contact: Oxidizing agents

Storage
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
Packaging material: Unsuitable material: None known.

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>PC-TWA</td>
<td>10 mg/m³</td>
<td>GBZ 2.1-2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Ezetimibe</td>
<td>163222-33-1</td>
<td>TWA</td>
<td>25 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>250 µg/100 cm²</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

Eye/face 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.

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

Hygiene measures:
- Consider double gloving.
- 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder

Colour: off-white

Odour: No data available

Odour Threshold: No data available
### 10. STABILITY AND REACTIVITY

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

Reactivity : Not classified as a reactivity hazard.
**Ezetimibe Formulation**

**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

**Exposure routes**
- 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
Ezetimibe Formulation

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 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:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

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
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 Formulation

Genotoxicity in vitro:
- **Ezetimibe**: 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:
- **Ezetimibe**: 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:
- **Ezetimibe**: 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
Ezetimibe Formulation

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  
  - **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
### Sodium n-dodecyl sulfate:

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Two-generation reproduction toxicity study</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 416</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Magnesium stearate:

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 422</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Repeated dose toxicity

### Components:

#### Cellulose:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>&gt;= 9,000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
</tbody>
</table>
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

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

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**

  - NOEC (Daphnia magna (Water flea)): 0.282 mg/l
  - Exposure time: 21 d
### Ezetimibe Formulation

**Version**: 3.0  
**Revision Date**: 09/13/2019  
**SDS Number**: 23826-00013  
**Date of last issue**: 2019/04/24  
**Date of first issue**: 2014/10/21

#### M-Factor (Chronic aquatic toxicity)

**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

#### 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

#### 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**

- EL50 (Pseudokirchneriella subcapitata (green algae)): > 1
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16 plants
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:
- Ezetimibe: log Pow: 4.36
- Sodium n-dodecyl sulfate: log Pow: 0.83
- Magnesium stearate: 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)
- 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): 956
SAFETY DATA SHEET
generated to GB/T 16483 and GB/T 17519

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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.

National Regulations:

GB 6944/12268
UN number: UN 3077
Proper shipping name:
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Ezetimibe)

Class:
9
Packing group:
III
Labels:
9

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 var-
iations in regional or country regulations.

15. REGULATORY INFORMATION

National regulatory information:
Law on the Prevention and Control of Occupational Diseases

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:
Sources of key data used to:
Internal technical data, data from raw material SDSs, OECD
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compile the Safety Data Sheet


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
GBZ 2.1-2007 / PC-TWA: Permissible concentration - 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 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; PCICS - 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

Disclaimer

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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