1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Ezetimibe Formulation

Manufacturer or supplier’s details
Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd.
Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASTEWARD@msd.com
Emergency telephone number: 1-908-423-6000

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
Important symptoms and outlines of the emergency assumed:
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

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 20 - &lt; 30</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ezetimibe</td>
<td>163222-33-1</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
<td>2</td>
<td></td>
<td>2-1679</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 10</td>
<td></td>
<td>2-611</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)

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 prod- : Carbon oxides
SAFETY DATA SHEET

Ezetimibe Formulation

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 as-
sessment
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

Hygiene measures

: Oxidizing agents
: 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.

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

Threshold limit value and permissible exposure limits for each component in the work en-
vironment

<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>
<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 con-
tainment devices).
  Minimize open handling.

Personal protective equipment

Respiratory protection

: If adequate local exhaust ventilation is not available or expo-
Filter type
Hand protection: Particulates type
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

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

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 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
Not classified based on available information.

## Components:

### Ezetimibe:
### 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
SAFETY DATA SHEET

Ezetimibe Formulation

Version: 5.0  Revision Date: 09/13/2019  SDS Number: 23837-00013  Date of last issue: 2019/04/24

Remarks:
Based on data from similar materials

Magnesium stearate:

<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>Method</td>
<td>OECD Test Guideline 406</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>
</tbody>
</table>

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

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 Test system: Human lymphocytes Result: negative</td>
</tr>
</tbody>
</table>

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

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>
</tbody>
</table>

| Genotoxicity in vivo | Test Type: Rodent dominant lethal test (germ cell) (in vivo) |

9 / 20
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 foetal development: Test Type: Fertility/early embryonic development
  Species: Rat
  Application Route: Ingestion
  Result: negative

Ezetimibe:
- Effects on fertility: Test Type: Fertility/early embryonic development
  Species: Rat, male and female
  Fertility: NOAEL: > 1,000 mg/kg body weight
  Result: No effects on fertility, No fetotoxicity
- Effects on foetal development: Test Type: Development
  Species: Rat
  Application Route: Oral
  Developmental Toxicity: NOAEL: > 1,000 mg/kg body weight
  Result: No adverse effects
  Test Type: Development
  Species: Rabbit
  Application Route: Oral
  Developmental Toxicity: NOAEL: > 1,000 mg/kg body weight
  Result: No adverse effects

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

Magnesium stearate:
- Effects on fertility: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
SAFETY DATA SHEET

Ezetimibe Formulation

Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on 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

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 : EC50 (Pseudokirchneriella subcapitata (green algae)): >
plants

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

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

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0.282 mg/l
- Exposure time: 21 d
- Method: OECD Test Guideline 209
- Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic toxicity): 1

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

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

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
## SAFETY DATA SHEET

**Ezetimibe 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>5.0</td>
<td>09/13/2019</td>
<td>23837-00013</td>
<td>2019/04/24</td>
<td>2014/10/21</td>
</tr>
</tbody>
</table>

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

**Toxicity to daphnia and other aquatic invertebrates**

- NOEC (Ceriodaphnia dubia (water flea)): 0.88 mg/l
- Exposure time: 7 d

### Toxicity to microorganisms

**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

**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

**Toxicity to algae/aquatic plants**

- 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:

Magnesium stearate:
- Biodegradability: 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:

Hazardous to the ozone layer
Not applicable

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, 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**
Refer to section 15 for specific national regulation.

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

15. REGULATORY INFORMATION

**Related Regulations**

**Fire Service Law**
Not applicable to dangerous materials / designated flammables.
Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium alkyl(C=8-18) sulfate</td>
<td>214</td>
</tr>
</tbody>
</table>

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
<td>&gt;=1 - &lt;10</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Class I Designated Chemical Substances

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
</table>
Sodium Lauryl Sulfate | 275 | 2.0

**High Pressure Gas Safety Act**
Not applicable

**Explosive Control Law**
Not applicable

**Vessel Safety Law**
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

**Aviation Law**
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

**Marine Pollution and Sea Disaster Prevention etc Law**
- Bulk transportation: Not classified as noxious liquid substance
- Pack transportation: Classified as marine pollutant

**Narcotics and Psychotropics Control Act**
Narcotic or Psychotropic Raw Material (Export / Import Permission)
- Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
- Not applicable

**Waste Disposal and Public Cleansing Law**
Industrial waste

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

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**16. OTHER INFORMATION**

**Further information**
Sources of key data used to 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
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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