SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ezetimibe Formulation

Version 3.2  Revision Date: 16.10.2020  SDS Number: 23842-00016  Date of last issue: 23.03.2020

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name: Ezetimibe Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet
Company: MSD
Shotton Lane
NE23 3JU Cramlington NU - Great Britain

Telephone: 44 1 670 59 30 00

Telefax: 908-735-1496

E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Long-term (chronic) aquatic hazard, Category 2

H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms:

Hazard statements: H411  Toxic to aquatic life with long lasting effects.

Precautionary statements:
Prevention:
P273  Avoid release to the environment.

Response:
P391  Collect spillage.
2.3 Other hazards
Dust contact with the eyes can lead to mechanical irritation.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ezetimibe</td>
<td>163222-33-1</td>
<td></td>
<td></td>
<td>Aquatic Chronic 1; H410</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>M-Factor (Chronic aquatic toxicity): 1</td>
<td></td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
<td>205-788-1</td>
<td>3</td>
<td>Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Aquatic Chronic 3; H412</td>
<td>&gt;= 1 - &lt; 2,5</td>
</tr>
<tr>
<td>2-Pyrrolidone</td>
<td>616-45-5</td>
<td>210-483-1</td>
<td>5</td>
<td>Eye Irrit. 2; H319 Repr. 1B; H360FD</td>
<td>&gt;= 0,1 - &lt; 0,3</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
                              Alcohol-resistant foam
                              Carbon dioxide (CO2)
                              Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions:
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.

Hygiene measures:
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working area.
7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types: Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<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>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>285 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>4060 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>85 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>2440 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>24 mg/kg bw/day</td>
</tr>
<tr>
<td>2-Pyrrolidone</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>57.8 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>10 mg/kg bw/day</td>
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<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>277 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>17.1 mg/m³</td>
</tr>
</tbody>
</table>
### 8.2 Exposure controls

#### 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

**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.

**Hand protection**

- Material: Chemical-resistant gloves

**Remarks**

- Consider double gloving.
- Work uniform or laboratory coat.

**Skin and body protection**

- Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable...
Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 14387 Filter type: Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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.
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:
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Viscosity, kinematic: No data available
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.

9.2 Other information
Flammability (liquids): No data available
Molecular weight: No data available
Particle size: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
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:

**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

**2-Pyrrolidone:**

- **Acute oral toxicity**
  - LD50 (Rat): > 2.000 mg/kg
    - Method: OECD Test Guideline 401
    - Assessment: The substance or mixture has no acute oral toxicity

- **Acute dermal toxicity**
  - LD50 (Rabbit): > 2.000 mg/kg
    - Method: OECD Test Guideline 402
    - Assessment: The substance or mixture has no acute dermal toxicity

**Skin corrosion/irritation**

Not classified based on available information.

Components:

**Ezetimibe:**

- **Species**: Rabbit
- **Result**: No skin irritation

**Sodium n-dodecyl sulfate:**

- **Species**: Rabbit
- **Result**: Skin irritation
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Species:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Result:
Result:
No skin irritation

Result:
Result:
No eye irritation

Result:
Result:
Irreversible effects on the eye

Result:
Result:
Irritation to eyes, reversing within 7 days

Result:
Result:
Based on data from similar materials

Result:
Result:
Based on data from similar materials

Result:
Result:
Local lymph node assay (LLNA)

Species:
Species:
Mouse

Species:
Species:
Guinea pig

Species:
Species:
Guinea pig

Exposure routes:
Exposure routes:
Skin contact
Exposure routes:
Exposure routes:
Skin contact

Exposure routes:
Exposure routes:
Skin contact

Exposure routes:
Exposure routes:
Skin contact

Exposure routes:
Exposure routes:
Skin contact
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Method: OECD Test Guideline 429
Result: negative
Remarks: Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

Components:

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

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

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

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

2-Pyrrolidone:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials
Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Carcinogenicity
Not classified based on available information.

Components:

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

2-Pyrrolidone:
Species: Mouse
Application Route: Ingestion
Exposure time: 18 month(s)
Result: negative
Remarks: Based on data from similar materials

Reproductive toxicity
Not classified based on available information.

Components:

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

2-Pyrrolidone:
Effects on fertility:
- Test Type: One-generation reproduction toxicity study
  Species: Rat
  Application Route: Ingestion
  Result: positive
  Remarks: Based on data from similar materials

Effects on foetal development:
- Test Type: Embryo-foetal development
  Species: Rat
  Application Route: Ingestion
  Result: positive

Reproductive toxicity - Assessment:
- Clear evidence of adverse effects on sexual function and fertility, based on animal experiments.
- Clear evidence of adverse effects on development, based on animal experiments.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:
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

**Components:**

**Ezetimibe:**

Not applicable

**Experience with human exposure**

**Components:**

**Ezetimibe:**

Ingestion: Symptoms: Headache, Nausea, Vomiting, Diarrhoea, flatus-

**Sodium n-dodecyl sulfate:**

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

**2-Pyrrolidone:**

Species: Rat  
NOAEL: 207 mg/kg  
Application Route: Ingestion  
Exposure time: 3 Months  
Method: OECD Test Guideline 408

**Aspiration toxicity**

Not classified based on available information.
SECTION 12: Ecological information

12.1 Toxicity

**Components:**

**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 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

- **Toxicity to fish (Chronic toxicity)**: NOEC: 0,051 mg/l
  - Exposure time: 33 d
  - Species: Pimephales promelas (fathead minnow)
  - Method: OECD Test Guideline 210

  NOEC: 4 mg/l
  - Exposure time: 7 d
  - Species: Cyprinodon variegatus (sheepshead minnow)
  - Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC: 0.282 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)
- Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic toxicity):
- 1

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 microorganisms:
  - EC50: 135 mg/l
  - Exposure time: 3 h

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC: 0.88 mg/l
- Exposure time: 7 d
- Species: Ceriodaphnia dubia (water flea)

2-Pyrrolidone:
- Toxicity to fish:
  - LC50 (Danio rerio (zebra fish)): > 4.600 - 10.000 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates:
  - EC50 (Daphnia magna (Water flea)): > 500 mg/l
  - Exposure time: 48 h
- Toxicity to algae/aquatic plants:
  - ErC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
  - Exposure time: 72 h
  - EC10 (Desmodesmus subspicatus (green algae)): 22,2 mg/l
  - Exposure time: 72 h
- Toxicity to microorganisms:
  - EC50: > 1.000 mg/l
  - Exposure time: 30 min
  - Method: OECD Test Guideline 209
12.2 Persistence and degradability

**Components:**

**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:**

**2-Pyrrolidone:**
- Biodegradability: Result: Readily biodegradable. Remarks: Based on data from similar materials

12.3 Bioaccumulative potential

**Components:**

**Ezetimibe:**
- Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish) Exposure time: 97 d Bioconcentration factor (BCF): 173 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

**2-Pyrrolidone:**
- Partition coefficient: n-octanol/water: log Pow: -0.71 Method: OECD Test Guideline 107

12.4 Mobility in soil

**Components:**

**Ezetimibe:**
- Distribution among environmental compartments: log Koc: 4.35 Method: OECD Test Guideline 106
12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

| ADN       | UN 3077 |
| ADR       | UN 3077 |
| RID       | UN 3077 |
| IMDG      | UN 3077 |
| IATA      | UN 3077 |

14.2 UN proper shipping name

| ADN       | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe) |
| ADR       | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe) |
| RID       | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe) |
| IMDG      | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe) |
| IATA      | Environmentally hazardous substance, solid, n.o.s. (Ezetimibe) |

14.3 Transport hazard class(es)

| ADN       | 9 |
| ADR       | 9 |
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ezetimibe Formulation

Version: 3.2
Revision Date: 16.10.2020
SDS Number: 23842-00016
Date of last issue: 23.03.2020
Date of first issue: 21.10.2014

RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

ADN
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

ADR
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

IMDG
Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)
Packing instruction (cargo aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes
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IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

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<th>ENVIRONMENTAL HAZARDS</th>
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The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical
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Full text of H-Statements
H302 : Harmful if swallowed.
H315 : Causes skin irritation.
H318 : Causes serious eye damage.
H319 : Causes serious eye irritation.
H360FD : May damage fertility. May damage the unborn child.
H410 : Very toxic to aquatic life with long lasting effects.
H412 : Harmful to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Dam. : Serious eye damage
Eye Irrit. : Eye irritation
Repr. : Reproductive toxicity
Skin Irrit. : Skin irritation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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 Bio-accumulative

Further information
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.