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

Ezetimibe Formulation

Version 3.3  Revision Date: 09.04.2021  SDS Number: 23833-00017  Date of last issue: 16.10.2020

Date of first issue: 21.10.2014

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: Organon & Co.
30 Hudson Street, 33nd floor
07302 Jersey City, New Jersey, U.S.A

Telephone: 551-430-6000

E-mail address of person responsible for the SDS: EHSSTEWARD@organon.com

1.4 Emergency telephone number

215-631-6999

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

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ezetimibe</td>
<td>163222-33-1</td>
<td>Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 1</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3 205-788-1</td>
<td>Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Aquatic Chronic 3; H412 specific concentration limit Eye Irrit. 2; H319 10 - &lt; 20 % Eye Dam. 1; H318 &gt;= 20 %</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
<tr>
<td></td>
<td>2-Pyrrolidone</td>
<td>616-45-5 210-483-1</td>
<td>Eye Irrit. 2; H319 Repr. 1B; H360FD specific concentration limit Repr. 1B; H360FD &gt; 3 %</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 fire-: Avoid generating dust; fine dust dispersed in air in sufficient
fighting 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.
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 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.

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

Occupational Exposure Limits

<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></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006

Ezetimibe Formulation

Version 3.3  Revision Date: 09.04.2021  SDS Number: 23833-00017  Date of last issue: 16.10.2020  Date of first issue: 21.10.2014

<table>
<thead>
<tr>
<th>Substance</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose 9004-34-6</td>
<td></td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Ezetimibe 163222-33-1</td>
<td>TWA</td>
<td>25 µg/m³ (OEB 3)</td>
<td>Internal</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate 557-04-0</td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 mg/m³</td>
<td>IE OEL</td>
<td></td>
</tr>
</tbody>
</table>

Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used.

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>Fresh water</td>
<td>0.176 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.018 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1.35 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>6.97 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.697 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>1.29 mg/kg dry</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

6 / 23
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ezetimibe Formulation

Version 3.3 Revision Date: 09.04.2021 SDS Number: 23833-00017 Date of last issue: 16.10.2020

<table>
<thead>
<tr>
<th>2-Pyrrolidone</th>
<th>Fresh water</th>
<th>0.5 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fresh water</td>
<td>0.5 mg/l</td>
<td></td>
</tr>
<tr>
<td>Marine water</td>
<td>0.05 mg/l</td>
<td></td>
</tr>
<tr>
<td>Sewage treatment plant</td>
<td>10 mg/l</td>
<td></td>
</tr>
<tr>
<td>Fresh water sediment</td>
<td>0.4205 mg/kg dry weight (d.w.)</td>
<td></td>
</tr>
<tr>
<td>Soil</td>
<td>0.0612 mg/kg dry weight (d.w.)</td>
<td></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.
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 degoowing techniques to remove potentially contaminated clothing.

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 I.S. 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
Physical state: powder
Colour: off-white
Odour: No data available
Odour Threshold: No data available
Melting point/freezing point: No data available
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ezetimibe Formulation

Version 3.3
Revision Date: 09.04.2021
SDS Number: 23833-00017
Date of last issue: 16.10.2020
Date of first issue: 21.10.2014

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial boiling point and boiling range</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>Flash point</td>
<td>Not applicable</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>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>No data available</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>Vapour pressure</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>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle characteristics</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

9.2 Other information

Explosives                                     : Not explosive
Oxidizing properties                           : The substance or mixture is not classified as oxidizing.
Evaporation rate                               : No data available
Molecular weight                               : 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 hazard classes as defined in Regulation (EC) No 1272/2008
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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ezetimibe Formulation

Version 3.3  Revision Date: 09.04.2021  SDS Number: 23833-00017  Date of last issue: 16.10.2020
Date of first issue: 21.10.2014

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

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

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components:**

**Ezetimibe:**
- Species: Rabbit
SAFETY DATA SHEET
generated according to Regulation (EC) No. 1907/2006

Ezetimibe Formulation

Version: 3.3
Revision Date: 09.04.2021
SDS Number: 23833-00017
Date of last issue: 16.10.2020
Date of first issue: 21.10.2014

Result : No eye irritation

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

2-Pyrrolidone:
Species : Rabbit
Result : Irritation to eyes, reversing within 7 days

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

2-Pyrrolidone:
Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
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)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Method: OECD Test Guideline 474  
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Ezetimibe:
Species: Rat, female  
Application Route: oral (feed)  
Exposure time: 104 weeks
**SAFETY DATA SHEET**
according to Regulation (EC) No. 1907/2006

**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>
</table>

**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**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species: Rat, male and female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fertility</td>
<td>NOAEL: &gt; 1,000 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>No effects on fertility, No fetotoxicity</td>
</tr>
</tbody>
</table>

**Effects on foetal development**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species: Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route: Oral</td>
<td>Oral</td>
</tr>
<tr>
<td>Developmental Toxicity</td>
<td>NOAEL: &gt; 1,000 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>No adverse effects</td>
</tr>
</tbody>
</table>

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

Ezetimibe Formulation

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

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.

Components:

Ezetimibe:
Not applicable

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

Components:

Ezetimibe:
Ingestion: Symptoms: Headache, Nausea, Vomiting, Diarrhoea, flatulence, muscle pain, upper respiratory tract infection, Back pain, joint pain
SECTION 12: Ecological information

12.1 Toxicity

Components:

**Ezetimibe:**
- 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
- 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
- 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
- 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
- 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
- To daphnia and other aquatic invertebrates (Chronic): NOEC: 0.282 mg/l
  - Exposure time: 21 d
ic toxicity)
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:**
Biodegradability : Result: Readily biodegradable.
Biodegradation: 95 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

**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

**Product:**
Assessment : This substance/mixture contains no components considered
to be either persistent, bioaccumulative and toxic (PBT), or
very persistent and very bioaccumulative (vPvB) at levels of
12.6 Endocrine disrupting properties

**Product:**

*Assessment* : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 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.

*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 or ID 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. |
IATA

**14.3 Transport hazard class(es)**

| ADN | 9 |
| ADR | 9 |
| 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 |
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 Maritime transport in bulk according to IMO instruments

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

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).</td>
<td>Not applicable</td>
</tr>
<tr>
<td>REACH - List of substances subject to authorisation (Annex XIV)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Regulation (EC) No 1005/2009 on substances that deplete the ozone layer</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Regulation (EU) 2019/1021 on persistent organic pollutants (recast)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>E2</th>
<th>ENVIRONMENTAL HAZARDS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quantity 1</td>
</tr>
<tr>
<td></td>
<td>200 t</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Inventory Code</th>
<th>Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ezetimibe Formulation

Version 3.3
Revision Date: 09.04.2021
SDS Number: 23833-00017
Date of last issue: 16.10.2020
Date of first issue: 21.10.2014

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

SECTION 16: Other information

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
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

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 (Adverse) 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 - (Quanti-
Further information
Sources of key data used to compile the Safety Data Sheet:

Classification of the mixture:
Aquatic Chronic 2 - H411

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.

IE / EN