1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Ezetimibe Formulation

Supplier's company name, address and phone number
Company name of supplier : Organon & Co.
Address : 30 Hudson Street, 33rd floor
           Jersey City, New Jersey, U.S.A 07302
Telephone : 551-430-6000
E-mail address : EHSSTEWARD@organon.com
Emergency telephone number : 215-631-6999

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
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.
SAFETY DATA SHEET

Ezetimibe Formulation

Version 7.1  Revision Date: 2020/10/16  SDS Number: 23837-00016  Date of last issue: 2020/03/23
Date of first issue: 2014/10/21

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cellulose</strong></td>
<td>&gt;= 20 - &lt; 30</td>
<td></td>
</tr>
<tr>
<td><strong>Ezetimibe</strong></td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>2</td>
<td>2-1679</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-611</td>
</tr>
<tr>
<td>2-Pyrrolidone</td>
<td>&gt;= 0.1 - &lt; 0.3</td>
<td>5-112</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air. Get medical attention if symptoms occur.

In case of skin contact: In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures**
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**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.

**Methods and materials for containment and cleaning up**
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
- Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

**Handling**

**Technical measures**
- Static electricity may accumulate and ignite suspended dust causing an explosion.
- Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

**Local/Total ventilation**
- Use only with adequate ventilation.

**Advice on safe handling**
- Do not get on skin or clothing.
- Do not breathe dust.
- Do not swallow.
- Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact: Oxidizing agents

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.

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 environment

<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 particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Engineering measures: All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

**Personal protective equipment**

**Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

**Filter type**: Combined particulates and organic vapour type

**Hand protection**

**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**

**Physical state**: powder

**Colour**: off-white

**Odour**: No data available

**Odour Threshold**: No data available

**Melting point/freezing point**: No data available

**Boiling point, initial boiling point and boiling range**: No data available

**Flammability (solid, gas)**: May form explosive dust-air mixture during processing, handling or other means.

**Flammability (liquids)**: No data available

**Lower explosion limit and upper explosion limit / flammability limit**

**Upper explosion limit / Upper flammability limit**: No data available

**Lower explosion limit / Lower flammability limit**: No data available

**Flash point**: Not applicable

**Decomposition temperature**: No data available
**10. STABILITY AND REACTIVITY**

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>Heat, flames and sparks.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Avoid dust formation.</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>Oxidizing agents</td>
</tr>
</tbody>
</table>

**11. TOXICOLOGICAL INFORMATION**

<table>
<thead>
<tr>
<th>Exposure Route</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information on likely routes of exposure</td>
<td>Inhalation</td>
</tr>
<tr>
<td></td>
<td>Skin contact</td>
</tr>
<tr>
<td></td>
<td>Ingestion</td>
</tr>
</tbody>
</table>
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

**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

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

Magnesium stearate:
Species: Rabbit
Result: No skin irritation
Remarks: Based on data from similar materials

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
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

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

Magnesium stearate:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

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.
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Ezetimibe Formulation

Components:

Cellulose:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: In vitro mammalian cell gene mutation test
  Result: negative

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

Ezetimibe:
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

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

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

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:

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
# SAFETY DATA SHEET

## Ezetimibe Formulation

**Version**
7.1

**Revision Date**
2020/10/16

**SDS Number**
23837-00016

**Date of last issue**
2020/03/23

**Date of first issue**
2014/10/21

---

**Sodium n-dodecyl sulfate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 453</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>

**2-Pyrrolidone:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>18 month(s)</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>

---

**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
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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:

Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
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:

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:

Cellulose:
Species: Rat
<table>
<thead>
<tr>
<th>Substance</th>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ezetimibe</td>
<td>Dog</td>
<td>1,000 mg/kg</td>
<td>Oral</td>
<td>90 d</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>1,500 mg/kg</td>
<td>Oral</td>
<td>90 d</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>500 mg/kg</td>
<td>Oral</td>
<td>90 d</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>Rat</td>
<td>488 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Rat</td>
<td>&gt; 100 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>2-Pyrrolidone</td>
<td>Rat</td>
<td>207 mg/kg</td>
<td>Ingestion</td>
<td>3 Months</td>
<td>OECD Test Guideline 408</td>
</tr>
</tbody>
</table>
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: 48 h
Method: OECD Test Guideline 203
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 4 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.317 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

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

Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 0.051 mg/l
Exposure time: 33 d
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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
Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic toxicity):
EC50: > 4.4 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

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

Sodium n-dodecyl sulfate:

Toxicity to fish:
LC50 (Pimephales promelas (fathead minnow)): 29 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants:
ErC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l
Exposure time: 72 h

NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l
Exposure time: 72 h

Toxicity to fish (Chronic toxicity):
NOEC (Pimephales promelas (fathead minnow)): > = 1.357 mg/l
Exposure time: 42 d

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

Toxicity to microorganisms:
EC50: 135 mg/l
Exposure time: 3 h

Magnesium stearate:

Toxicity to fish:
LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
Exposure time: 48 h
Method: DIN 38412
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:
EL50 (Daphnia magna (Water flea)): > 1 mg/l
aquatic invertebrates
Exposure time: 47 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

Toxicity to algae/aquatic plants
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

2-Pyrrolidone:
Toxicity to fish
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 203

Toxicity to algae/aquatic plants
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 203

Toxicity to microorganisms
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 203

Persistence and degradability

Components:

Cellulose:
Biodegradability: Result: Readily biodegradable.

Ezetimibe:
Biodegradability: Result: Not readily biodegradable.
SAFETY DATA SHEET

Ezetimibe Formulation

Biodegradation: 6.8 %
Exposure time: 28 d

Stability in water:
Hydrolysis: 50 % (4.5 d)
Method: OECD Test Guideline 111

Sodium n-dodecyl sulfate:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 95 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Magnesium stearate:
Biodegradability: Result: Not biodegradable
Remarks: Based on data from similar materials

2-Pyrrolidone:
Biodegradability: Result: Readily 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

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

Mobility in soil

Components:

Ezetimibe:
Distribution among environmental compartments:
log Koc: 4.35
Method: OECD Test Guideline 106
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.
SAFETY DATA SHEET

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Version 7.1    Revision Date: 2020/10/16    SDS Number: 23837-00016    Date of last issue: 2020/03/23
Date of first issue: 2014/10/21

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>
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</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
<td>&gt;=1 - &lt;10</td>
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</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
16. OTHER INFORMATION

Further information
SAFETY DATA SHEET

Ezetimibe Formulation

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Sources of key data used to compile the Safety Data Sheet:

Date format: yyyy/mm/dd

Full text of other abbreviations:
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA: 8-hour, time-weighted average

All other abbreviations are defined in the document. For example:
- IC50: Half maximal inhibitory concentration
- LD50: Lethal Dose to 50% of a test population (Median Lethal Dose)
- LC50: Lethal Concentration to 50% of a test population
- NO(A)EC: No Observed (Adverse) Effect Concentration
- NO(A)EL: No Observed (Adverse) Effect Level
- NOE: No Observable Effect Loading Rate

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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