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

Ezetimibe Granules Formulation

Version 2.5   Revision Date: 10.10.2020   SDS Number: 1567799-00008   Date of last issue: 23.03.2020
Date of first issue: 18.04.2017

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

1.1 Product identifier
Trade name: Ezetimibe Granules 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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</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></td>
<td>Aquatic Chronic 1; H410</td>
<td>&gt;= 2,5 - &lt; 10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></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></td>
<td></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>
</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 place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
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>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>
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</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>
</tbody>
</table>

**Predicted No Effect Concentration (PNEC) 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 weight (d.w.)</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

**Engineering measures**
Ensure adequate ventilation, especially in confined areas.
Minimize workplace exposure concentrations.
Apply measures to prevent dust explosions.
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

**Personal protective equipment**

<table>
<thead>
<tr>
<th>Protection</th>
<th>Required Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Eye protection</strong></td>
<td>Wear the following personal protective equipment:</td>
</tr>
<tr>
<td></td>
<td>Safety goggles</td>
</tr>
<tr>
<td></td>
<td>Equipment should conform to NS EN 166</td>
</tr>
<tr>
<td><strong>Hand protection</strong></td>
<td>Material: Chemical-resistant gloves</td>
</tr>
<tr>
<td><strong>Remarks</strong></td>
<td>Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.</td>
</tr>
<tr>
<td><strong>Skin and body protection</strong></td>
<td>Skin should be washed after contact.</td>
</tr>
<tr>
<td><strong>Respiratory protection</strong></td>
<td>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 143</td>
</tr>
<tr>
<td><strong>Filter type</strong></td>
<td>Particulates type (P)</td>
</tr>
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</table>

**SECTION 9: Physical and chemical properties**

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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<tbody>
<tr>
<td>Appearance</td>
<td>granular</td>
</tr>
<tr>
<td>Colour</td>
<td>white</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
</tbody>
</table>
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
Density : No data available
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.

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): 1.200 mg/kg
Method: OECD Test Guideline 401

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

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

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
Method : OECD Test Guideline 405
Result : Irreversible effects on the eye

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

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

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
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**Sodium n-dodecyl sulfate:**
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Method: OECD Test Guideline 453
Result: negative
Remarks: Based on data from similar materials

**Reproductive toxicity**
Not classified based on available information.

**Components:**

**Ezetimibe:**
Effects on fertility:
Species: Rat, male and female
Fertility: NOAEL: > 1.000 mg/kg body weight
Result: No effects on fertility, No fetotoxicity

Effects on foetal 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:
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development:
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

**STOT - single exposure**
Not classified based on available information.

**STOT - repeated exposure**
Not classified based on available information.
Repeated dose toxicity

**Components:**

**Ezetimibe:**
- **Species:** Dog
- **NOAEL:** 1.000 mg/kg
- **Application Route:** Oral
- **Exposure time:** 90 d
- **Remarks:** No significant adverse effects were reported

- **Species:** Rat
- **NOAEL:** 1.500 mg/kg
- **Application Route:** Oral
- **Exposure time:** 90 d
- **Remarks:** No significant adverse effects were reported

- **Species:** Mouse
- **NOAEL:** 500 mg/kg
- **Application Route:** Oral
- **Exposure time:** 90 d
- **Remarks:** No significant adverse effects were reported

- **Species:** Dog
- **NOAEL:** 300 mg/kg
- **Application Route:** Oral
- **Exposure time:** 1 yr
- **Remarks:** No significant adverse effects were reported

**Sodium n-dodecyl sulfate:**
- **Species:** Rat
- **NOAEL:** 488 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 90 Days
- **Remarks:** Based on data from similar materials

**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
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
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)

**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:**


**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

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 Granules Formulation

**Version** | **Revision Date** | **SDS Number** | **Date of last issue**  | **Date of first issue**
---|---|---|---|---
2.5 | 10.10.2020 | 1567799-00008 | 23.03.2020 | 18.04.2017

### 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)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
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<tr>
<td>ADR</td>
<td>9</td>
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<td>RID</td>
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</tr>
<tr>
<td>IMDG</td>
<td>9</td>
</tr>
<tr>
<td>IATA</td>
<td>9</td>
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</tbody>
</table>

### 14.4 Packing group

<p>| | |</p>
<table>
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<th></th>
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</thead>
<tbody>
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<tr>
<td>Packing group</td>
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<td>Packing group</td>
<td>III</td>
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<td>Classification Code</td>
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<td>Tunnel restriction code</td>
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<td><strong>RID</strong></td>
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<tr>
<td>Packing group</td>
<td>III</td>
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<td>Classification Code</td>
<td>M7</td>
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<tr>
<td>Hazard Identification Number</td>
<td>90</td>
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<tr>
<td>Labels</td>
<td>9</td>
</tr>
<tr>
<td><strong>IMDG</strong></td>
<td></td>
</tr>
<tr>
<td>Packing group</td>
<td>III</td>
</tr>
<tr>
<td>Labels</td>
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<tr>
<td>Ems Code</td>
<td>F-A, S-F</td>
</tr>
<tr>
<td><strong>IATA (Cargo)</strong></td>
<td></td>
</tr>
<tr>
<td>Packing instruction (cargo aircraft)</td>
<td>956</td>
</tr>
<tr>
<td>Packing instruction (LQ)</td>
<td>Y956</td>
</tr>
<tr>
<td>Packing group</td>
<td>III</td>
</tr>
<tr>
<td>Labels</td>
<td>Miscellaneous</td>
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</tbody>
</table>
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

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

Ezetimibe Granules Formulation

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E2

ENVIRONMENTAL HAZARDS

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 lines.

Full text of H-Statements

H302:
Harmful if swallowed.

H315:
Causes skin irritation.

H318:
Causes serious eye damage.

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

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;
EC No 1272/2008 - European Regulation;
EC - 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);
E-Chemical - European Chemicals Agency;
EC Number - European Community number;
ECx - Concentration associated with x% response;
GHS - Globally Harmonized System;
GLP - Good Laboratory Practice;
ICAO - International Civil Aviation Organization;
ICBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk;
IC50 - Half maximal inhibitory concentration;
IC50 - Lethal Concentration to 50% of a test population;
IC50 - Lethal Dose to 50% of a test population (Median Lethal Dose);
IARC - International Agency for Research on Cancer;
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;
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
Ezetimibe Granules Formulation

Version 2.5 Revision Date: 10.10.2020 SDS Number: 1567799-00008 Date of last issue: 23.03.2020 Date of first issue: 18.04.2017

Further information

Classification of the mixture: Aquatic Chronic 2 H411 Classification procedure: Calculation method

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.

NO / EN