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

Ezetimibe / Rosuvastatin Formulation

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

1.1 Product identifier
   Trade name : Ezetimibe / Rosuvastatin 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
   Innishannon
   County Cork - Ireland
   Telephone : 353 214329300
   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)
   Carcinogenicity, Category 1B : H350: May cause cancer.
   Reproductive toxicity, Category 1B : H360FD: May damage fertility. May damage the unborn child.
   Specific target organ toxicity - single exposure, Category 2 : H371: May cause damage to organs.
   Specific target organ toxicity - repeated exposure, Category 2 : H373: May cause damage to organs through prolonged or repeated exposure.
   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 : 
   Signal word : Danger
   Hazard statements : H350 May cause cancer.
H360FD May damage fertility. May damage the unborn child.
H371 May cause damage to organs.
H373 May cause damage to organs through prolonged or repeated exposure.
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements:

**Prevention:**
P201 Obtain special instructions before use.
P260 Do not breathe dust.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

**Response:**
P308 + P311 IF exposed or concerned: Call a POISON CENTER/doctor.
P391 Collect spillage.

**Hazardous components which must be listed on the label:**
Rosuvastatin

**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>Components</th>
<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></td>
<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></td>
<td>M-Factor (Chronic aquatic toxicity): 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rosuvastatin</td>
<td>147098-20-2</td>
<td></td>
<td></td>
<td></td>
<td>Carc. 1B; H350 Repr. 1B; H360FD STOT SE 1; H370 (Liver, Kidney, muscle) STOT RE 1; H372 (Eye) 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></td>
<td>M-Factor (Chronic</td>
<td></td>
</tr>
</tbody>
</table>
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.

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. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks: May cause cancer. May damage fertility. May damage the unborn child. May cause damage to organs. May cause damage to organs through prolonged or repeated exposure. 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
Fluorine compounds
Nitrogen oxides (NOx)
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:
- If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe dust.
- Do not swallow.
- Avoid contact with eyes.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- 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.
- Do not eat, drink or smoke when using this product.
- 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.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ezetimibe / Rosuvastatin Formulation

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Occupational Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>Cellulose</td>
</tr>
<tr>
<td>Ezetimibe</td>
</tr>
<tr>
<td>Rosuvastatin</td>
</tr>
<tr>
<td>Magnesium stearate</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>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>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ezetimibe / Rosuvastatin Formulation

Version 1.6  Revision Date: 10.10.2020  SDS Number: 3178916-00007  Date of last issue: 23.03.2020  Date of first issue: 18.09.2018

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
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 degowning 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 143

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : powder
Colour : white to off-white
Odour : No data available
Odour Threshold : No data available
### Ezetimibe / Rosuvastatin Formulation

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<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>Not applicable</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>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>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</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>Solubility(ies)</td>
<td>Water solubility: No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</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>Viscosity</td>
<td>Viscosity, kinematic: Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>

### 9.2 Other information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>
**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**

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Inhalation</th>
<th>Skin contact</th>
<th>Ingestion</th>
<th>Eye contact</th>
</tr>
</thead>
</table>

**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
Ezetimibe / Rosuvastatin Formulation

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

Rosuvastatin:
- Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
  Target Organs: Liver, Stomach, muscle, Kidney

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

### Rosuvastatin:
- **Genotoxicity in vitro:**
  - **Test Type:** Bacterial reverse mutation assay (AMES)
  - **Test system:** Escherichia coli
  - **Result:** negative
- **Genotoxicity in vivo:**
  - **Test Type:** Micronucleus test
  - **Species:** Mouse
  - **Cell type:** Bone marrow
  - **Application Route:** Ingestion
  - **Result:** negative
# Ezetimibe / Rosuvastatin Formulation

### Sodium n-dodecyl sulfate:

**Genotoxicity in vitro**
- **Test Type:** Bacterial reverse mutation assay (AMES)
- **Method:** OECD Test Guideline 471
- **Result:** negative

**Genotoxicity in vivo**
- **Test Type:** In vitro mammalian cell gene mutation test
- **Result:** negative

### Carcinogenicity

May cause cancer.

### 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

#### Rosuvastatin:

- **Species:** Rat
- **Application Route:** Oral
- **Exposure time:** 104 weeks
- **LOAEL:** 80 mg/kg body weight
- **Result:** positive
- **Symptoms:** Tumour
- **Target Organs:** Uterus (including cervix)

- **Species:** Mouse
- **Application Route:** Oral
- **Exposure time:** 107 weeks
- **LOAEL:** 200 mg/kg body weight
- **Result:** positive
- **Symptoms:** liver adenoma, carcinoma
- **Target Organs:** Liver
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
May damage fertility. May damage the unborn child.

Components:

Ezetimibe:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat, male and female
Fertility: NOAEL: > 1,000 mg/kg body weight
 Result: No effects on fertility, No fetotoxicity

Effects on foetal development: Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: > 1,000 mg/kg body weight
Result: No adverse effects

Rosuvastatin:
Effects on fertility: Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 50 mg/kg body weight

Test Type: Fertility
Species: Monkey
Application Route: Oral
Fertility: LOAEL: 30 mg/kg body weight
Result: Effects on male and female reproductive organs.

Effects on foetal development: Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 50 mg/kg body weight
Result: foetal mortality

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 3 mg/kg body weight
Reproductive toxicity - Assessment: May damage fertility. May damage the unborn child.

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

STOT - single exposure
May cause damage to organs.

Components:

Rosuvastatin:
Exposure routes: Oral
Target Organs: Liver, Kidney, muscle
Assessment: Causes damage to organs.

STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.

Components:

Rosuvastatin:
Exposure routes: Oral
Target Organs: Eye
Assessment: Causes damage to organs through prolonged or repeated exposure.

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
<table>
<thead>
<tr>
<th>Application Route</th>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Symptoms</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>Mouse</td>
<td>500 mg/kg</td>
<td>Oral</td>
<td>90 d</td>
<td></td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>300 mg/kg</td>
<td>Oral</td>
<td>1 yr</td>
<td></td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>90 mg/kg</td>
<td>Oral</td>
<td>24 Days</td>
<td>Oedema, Blood disorders, Necrosis</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>6 mg/kg</td>
<td>Oral</td>
<td>52 Weeks</td>
<td>Corneal opacity</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>30 mg/kg</td>
<td>Oral</td>
<td>12 Weeks</td>
<td>Eye disease</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>90 mg/kg</td>
<td>Oral</td>
<td>4 Weeks</td>
<td>Eye - retina</td>
<td>Eye disease</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>488 mg/kg</td>
<td>Ingestion</td>
<td></td>
<td></td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**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

**Rosuvastatin:**
**Ingestion**
Target Organs: Kidney
Symptoms: kidney toxicity
Remarks: Based on Human Evidence
Target Organs: muscle
Symptoms: musculoskeletal pain
Remarks: Based on Human Evidence
Target Organs: Liver
Symptoms: liver function change
Remarks: Based on Human Evidence

**SECTION 12: Ecological information**

**12.1 Toxicty**

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

### Ezetimibe / Rosuvastatin Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.6</td>
<td>10.10.2020</td>
<td>3178916-00007</td>
<td>23.03.2020</td>
<td>18.09.2018</td>
</tr>
</tbody>
</table>

#### 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

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

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

#### M-Factor (Chronic aquatic toxicity):
- 1

**Rosuvastatin:**

#### Toxicity to fish:
- LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l
- Exposure time: 96 hrs
- Method: FDA 4.11

- LC50 (Lepomis macrochirus (Bluegill sunfish)): > 1,000 mg/l
- Exposure time: 96 hrs
- Method: FDA 4.11

#### Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): 63 mg/l
- Exposure time: 48 hrs
- Method: OECD Test Guideline 202

#### Toxicity to algae/aquatic plants:
- EC50 (Microcystis aeruginosa (blue-green algae)): > 640 mg/l
- Exposure time: 96 hrs
- Method: FDA 4.01
NOEC (Microcystis aeruginosa (blue-green algae)): 330 mg/l
Exposure time: 96 hrs
Method: FDA 4.01

EC50 (Pseudokirchneriella subcapitata (green algae)): > 800 mg/l
Exposure time: 96 hrs
Method: FDA 4.01

NOEC (Pseudokirchneriella subcapitata (green algae)): 350 mg/l
Exposure time: 96 hrs
Method: FDA 4.01

Toxicity to microorganisms: EC50: > 100 mg/l
Exposure time: 3 hrs
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 100 mg/l
Exposure time: 3 hrs
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity): NOEC: 1 mg/l
Exposure time: 32 Days
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 0.018 mg/l
Exposure time: 21 Days
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

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
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

**Rosuvastatin:**
- **Biodegradability:** Biodegradation: < 10 %
  - Exposure time: 28 Days
  - Method: OECD Test Guideline 301F
  - Remarks: Not inherently biodegradable.

**Stability in water:**
- Hydrolysis: < 10 % (5 Days)

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

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:**
- log Pow: 4.36

**Rosuvastatin:**
- **Partition coefficient:** log Pow: 0.3

**Sodium n-dodecyl sulfate:**
- **Partition coefficient:** log Pow: 0.83
12.4 Mobility in soil

Components:

Ezetimibe:
Distribution among environmental compartments: log Koc: 4.35
Method: OECD Test Guideline 106

Rosuvastatin:
Distribution among environmental compartments: log Koc: 2.15
Method: FDA 3.08

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, Rosuvastatin)
ADR: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe, Rosuvastatin)
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ezetimibe / Rosuvastatin Formulation

Version 1.6
Revision Date: 10.10.2020
SDS Number: 3178916-00007
Date of last issue: 23.03.2020
Date of first issue: 18.09.2018

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

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
Ezetimibe / Rosuvastatin Formulation

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


<table>
<thead>
<tr>
<th>E2</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>200 t</td>
<td>500 t</td>
</tr>
</tbody>
</table>

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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.
- H350: May cause cancer.
- H360FD: May damage fertility. May damage the unborn child.
- H370: Causes damage to organs if swallowed.
- H372: Causes damage to organs through prolonged or repeated exposure if swallowed.
- 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
- Carc.: Carcinogenicity
- Eye Dam.: Serious eye damage
- Repr.: Reproductive toxicity
- Skin Irrit.: Skin irritation
- STOT RE: Specific target organ toxicity - repeated exposure
- STOT SE: Specific target organ toxicity - single exposure
- 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 - Con-
Further information


Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification of the mixture</th>
<th>Classification procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carc. 1B</td>
<td>H350</td>
</tr>
<tr>
<td>Repr. 1B</td>
<td>H360FD</td>
</tr>
<tr>
<td>STOT SE 2</td>
<td>H371</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
</tr>
<tr>
<td>Aquatic Chronic 2</td>
<td>H411</td>
</tr>
</tbody>
</table>

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