SAFETY DATA SHEET
Ezetimibe / Rosuvastatin Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ezetimibe / Rosuvastatin Formulation

Manufacturer or supplier’s details
Company : Organon & Co.
Address : 30 Hudson Street, 33nd floor
            Jersey City, New Jersey, U.S.A 07302
Telephone : 551-430-6000
Emergency telephone number : 215-631-6999
E-mail address : EHSSTEWARD@organon.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Carcinogenicity : Category 1B
Reproductive toxicity : Category 1B
Specific target organ toxicity - single exposure (Oral) : Category 2 (Liver, Kidney, muscle)
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Eye)

GHS label elements
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 (Liver, Kidney, muscle) if swallowed.
                   H373 May cause damage to organs (Eye) through prolonged or repeated exposure if swallowed.

Precautionary statements : Prevention:
                          P201 Obtain special instructions before use.
                          P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P281 Use personal protective equipment as required.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

Other hazards which do not result in classification
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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>≥ 10 &lt; 30</td>
</tr>
<tr>
<td>Ezetimibe</td>
<td>163222-33-1</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Rosuvastatin</td>
<td>147098-20-2</td>
<td>≥ 1 &lt; 10</td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
<td>≥ 1 &lt; 3</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&lt; 10</td>
</tr>
</tbody>
</table>

SECTION 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.
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.
Most important symptoms and effects, both acute and: May cause cancer. May damage fertility. May damage the unborn child.
delayed  May cause damage to organs if swallowed.
          May cause damage to organs through prolonged or repeated
          exposure if swallowed.
          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.

SECTION 5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media  : None known.

Specific hazards during fire-fighting  : 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

Specific extinguishing methods  : Use extinguishing measures that are appropriate to local cir-
                                   cumstances 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.

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

Hazchem Code  : 2Z

SECTION 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 con-
                                                  tainer 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 surfac-
es, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

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.

Conditions for safe storage
- Keep in properly labelled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

Materials to avoid
- Do not store with the following product types:
  - Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters
## Components

<table>
<thead>
<tr>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
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</thead>
<tbody>
<tr>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td>163222-33-1</td>
<td>TWA</td>
<td>25 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td>147098-20-2</td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td>557-04-0</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>AU OEL</td>
</tr>
</tbody>
</table>

Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica.

<table>
<thead>
<tr>
<th>TWA</th>
<th>10 mg/m³</th>
<th>ACGIH</th>
</tr>
</thead>
</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**: Particulates type

#### Hand protection

Material: Chemical-resistant gloves

**Remarks**: Consider double gloving.

#### Eye protection

**Material**: Chemical-resistant glasses

**Remarks**: 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

**Material**: Work uniform or laboratory coat

**Remarks**: 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.
SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder
Colour : white to off-white
Odour : No data available
Odour Threshold : No data available
pH : No data available
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : Not applicable
Evaporation rate : Not applicable
Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapour pressure : Not applicable
Relative vapour density : Not applicable
Relative density : No data available
Density : No data available
Solubility(ies)
   Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
   Viscosity, kinematic : Not applicable
Explosive properties : Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.

Molecular weight: No data available

Particle size: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.

Chemical stability: Stable under normal conditions.

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

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

Incompatible materials: Oxidizing agents

Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes: 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:
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

**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

**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

**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

**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

**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

**Chronic toxicity**

**Germ cell mutagenicity**
Not classified based on available information.
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

Rosuvastatin:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Test system: Escherichia coli Result: negative
                         Test Type: Chromosomal aberration Test system: Chinese hamster lung cells Result: negative
Genotoxicity in vivo   : Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Application Route: Ingestion 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

Carcinogenicity:
May cause cancer.

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

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:

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
### 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  
  Result: foetal mortality, Maternal toxicity observed.

- 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

### Magnesium stearate:

**Effects on fertility**
- 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
STOT - single exposure
May cause damage to organs (Liver, Kidney, muscle) if swallowed.

**Components:**

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

STOT - repeated exposure
May cause damage to organs (Eye) through prolonged or repeated exposure if swallowed.

**Components:**

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

Repeated dose toxicity

**Components:**

**Cellulose:**
- Species: Rat
- NOAEL: >= 9,000 mg/kg
- Application Route: Ingestion
- Exposure time: 90 Days

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

Rosuvastatin:
Species: Dog
LOAEL: 90 mg/kg
Application Route: Oral
Exposure time: 24 Days
Target Organs: Brain
Symptoms: Oedema, Blood disorders, Necrosis
Remarks: Based on data from similar materials

Species: Dog
LOAEL: 6 mg/kg
Application Route: Oral
Exposure time: 52 Weeks
Target Organs: Cornea
Symptoms: Corneal opacity
Remarks: Based on data from similar materials

Species: Dog
LOAEL: 30 mg/kg
Application Route: Oral
Exposure time: 12 Weeks
Target Organs: Eye
Symptoms: Eye disease
Remarks: Based on data from similar materials

Species: Dog
LOAEL: 90 mg/kg
Application Route: Oral
Exposure time: 4 Weeks
Target Organs: eye - retina
Symptoms: Eye disease
Remarks: Based on data from similar materials

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

Magnesium stearate:
Species: Rat
NOAEL: > 100 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

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: 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 fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.051 mg/l
Exposure time: 33 d
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

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

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
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<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>
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<tbody>
<tr>
<td>1.6</td>
<td>10.10.2020</td>
<td>3177573-00007</td>
<td>23.03.2020</td>
<td>18.09.2018</td>
</tr>
</tbody>
</table>

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

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

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

### 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
- **Test substance**: Water Accommodated Fraction
- **Exposure time**: 47 h

#### Toxicity to algae/aquatic plants
- **Test substance**: Water Accommodated Fraction
- **Exposure time**: 72 h
- **Method**: OECD Test Guideline 201

#### Toxicity to microorganisms
- **Test substance**: Water Accommodated Fraction

### Persistence and degradability

#### Components:

#### Cellulose:
- **Biodegradability**: Result: Readily biodegradable.

#### 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

**Magnesium stearate:**
Biodegradability: Result: Not 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

**Rosuvastatin:**
Partition coefficient: n-octanol/water: log Pow: 0.3

**Sodium n-dodecyl sulfate:**
Partition coefficient: n-octanol/water: log Pow: 0.83

**Magnesium stearate:**
Partition coefficient: n-octanol/water: log Pow: > 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

### Other adverse effects
No data available

### SECTION 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.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe, Rosuvastatin)
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, Rosuvastatin)
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, Rosuvastatin)
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

ADG
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe, Rosuvastatin)
Class: 9
Packing group: III
Labels: 9
Hazchem Code: 2Z
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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Prohibition/Licensing Requirements: There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

SECTION 16. OTHER INFORMATION

Further information

Revision Date: 10.10.2020

Date format: dd.mm.yyyy

Full text of other abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>AU OEL</td>
<td>Australia. Workplace Exposure Standards for Airborne Contaminants.</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>AU OEL / TWA</td>
<td>Exposure standard - time weighted average</td>
</tr>
</tbody>
</table>

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA
SAFETY DATA SHEET
Ezetimibe / Rosuvastatin Formulation

Version 1.6  
Revision Date: 10.10.2020  
SDS Number: 3177573-00007  
Date of last issue: 23.03.2020  
Date of first issue: 18.09.2018

- International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

AU / EN