SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ezetimibe / Rosuvastatin Formulation

Manufacturer or supplier’s details
Company name of supplier : Organon & Co.
Address : Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone : 52 55 57284444
Emergency telephone : 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
Skin irritation : Category 3
Carcinogenicity : Category 1B
Reproductive toxicity : Category 1B
Specific target organ toxicity - single exposure (Oral) : Category 1 (Liver, Kidney, muscle)
Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Eye)

GHS label elements
Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H316 Causes mild skin irritation.
H350 May cause cancer.
H360FD May damage fertility. May damage the unborn child.
H370 Causes damage to organs (Liver, Kidney, muscle) if swallowed.
H372 Causes 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.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.

Storage:
P405 Store locked up.

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

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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Cellulose</td>
</tr>
<tr>
<td></td>
<td>Ezetimibe</td>
</tr>
<tr>
<td></td>
<td>Rosuvastatin</td>
</tr>
<tr>
<td></td>
<td>Sodium n-dodecyl sulfate</td>
</tr>
<tr>
<td></td>
<td>Magnesium stearate</td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Ezetimibe</td>
<td>163222-33-1</td>
</tr>
<tr>
<td>Rosuvastatin</td>
<td>147098-20-2</td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</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 : Causes mild skin irritation. May cause cancer.
SECTION 5. FIRE-FIGHTING 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)
- Sulfur oxides
- Metal oxides

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.

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

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

### SECTION 7. HANDLING AND STORAGE

<table>
<thead>
<tr>
<th>Technical measures</th>
<th>Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local/Total ventilation</td>
<td>If sufficient ventilation is unavailable, use with local exhaust ventilation.</td>
</tr>
<tr>
<td>Advice on safe handling</td>
<td>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.</td>
</tr>
<tr>
<td>Hygiene measures</td>
<td>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 decontamination and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.</td>
</tr>
<tr>
<td>Conditions for safe storage</td>
<td>Keep in properly labeled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.</td>
</tr>
<tr>
<td>Materials to avoid</td>
<td>Do not store with the following product types: Strong oxidizing agents Organic peroxides Explosives Gases</td>
</tr>
</tbody>
</table>
SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>VLE-PPT</td>
<td>10 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Ezetimibe</td>
<td>163222-33-1</td>
<td>TWA</td>
<td>25 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>250 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Rosuvastatin</td>
<td>147098-20-2</td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>200 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>VLE-PPT</td>
<td>10 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

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

Personal protective equipment

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

Filter type: Particulates type

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

Eye protection:
Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection:
Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Color</td>
<td>white to off-white</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor 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>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>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapor 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</td>
</tr>
<tr>
<td></td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition 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</td>
</tr>
<tr>
<td></td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
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

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: > 5,000 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
SAFETY DATA SHEET
Ezetimibe / Rosuvastatin Formulation

Version: 1.6
Revision Date: 10.10.2020
SDS Number: 3177577-00007
Date of last issue: 23.03.2020
Date of first issue: 18.09.2018

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
Causes mild skin irritation.

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 sensitization**

**Skin sensitization**
Not classified based on available information.

**Respiratory sensitization**
Not classified based on available information.

**Components:**

**Ezetimibe:**
Test Type: Maximization Test
Species: Guinea pig
Result: negative

**Sodium n-dodecyl sulfate:**
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

**Magnesium stearate:**
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials
Germ cell mutagenicity
Not classified based on available information.

**Components:**

**Cellulose:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

**Ezetimibe:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Metabolic activation: with and without metabolic activation</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Test Type: Chromosomal aberration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test system: Human lymphocytes</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Micronucleus test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Cell type: Bone marrow</td>
</tr>
<tr>
<td></td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

**Rosuvastatin:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test system: Escherichia coli</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Test Type: Chromosomal aberration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test system: Chinese hamster lung cells</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Micronucleus test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Cell type: Bone marrow</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

**Sodium n-dodecyl sulfate:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Method: OECD Test Guideline 471</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>
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
SAFETY DATA SHEET
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>3177577-00007</td>
<td>23.03.2020</td>
<td>18.09.2018</td>
</tr>
</tbody>
</table>

**Exposure time**: 104 weeks
**LOAEL**: 80 mg/kg body weight
**Result**: positive
**Symptoms**: Tumor
**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 fetal 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 fetal 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 fetal development:
- Test Type: Development
  - Species: Rat
  - Application Route: Oral
  - Developmental Toxicity: LOAEL: 50 mg/kg body weight
  - Result: Fetal mortality.

- Test Type: Development
  - Species: Rabbit
  - Application Route: Oral
  - Developmental Toxicity: LOAEL: 3 mg/kg body weight
  - Result: Fetal 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 fetal development:
- Test Type: Embryo-fetal 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 fetal development:
- Test Type: Embryo-fetal development
STOT-single exposure
Causes damage to organs (Liver, Kidney, muscle) if swallowed.

Components:
Rosuvastatin:
Routes of exposure: Oral
Target Organs: Liver, Kidney, muscle
Assessment: Causes damage to organs.

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

Components:
Rosuvastatin:
Routes of exposure: 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

**Species**

Dog

**NOAEL**

300 mg/kg

**Application Route**

Oral

**Exposure time**

1 y

**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

Edema, 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, Diarrhea, 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
### Toxicity to fish (Chronic toxicity)

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):

<table>
<thead>
<tr>
<th>Substance</th>
<th>Effect Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ezetimibe / Rosuvastatin</td>
<td>NOEC</td>
</tr>
<tr>
<td></td>
<td>(Pimephales promelas (fathead minnow)): 0.051 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 33 d</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 210</td>
</tr>
<tr>
<td></td>
<td>NOEC (Cyprinodon variegatus (sheepshead minnow)): 4 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 7 d</td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

<table>
<thead>
<tr>
<th>Substance</th>
<th>Effect Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NOEC</td>
</tr>
<tr>
<td></td>
<td>(Daphnia magna (Water flea)): 0.282 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

Toxicity to microorganisms:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Effect Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EC50: &gt; 4.4 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td></td>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 209</td>
</tr>
<tr>
<td></td>
<td>NOEC: 4.4 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td></td>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

**Rosuvastatin:**

Toxicity to fish:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Effect Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LC50 (Pimephales promelas (fathead minnow)): &gt; 1,000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 hrs</td>
</tr>
<tr>
<td></td>
<td>Method: FDA 4.11</td>
</tr>
<tr>
<td></td>
<td>LC50 (Lepomis macrochirus (Bluegill sunfish)): &gt; 1,000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 hrs</td>
</tr>
<tr>
<td></td>
<td>Method: FDA 4.11</td>
</tr>
</tbody>
</table>

Toxicity to daphnia and other aquatic invertebrates:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Effect Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EC50 (Daphnia magna (Water flea)): 63 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 48 hrs</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

Toxicity to algae/aquatic plants:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Effect Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EC50 (Microcystis aeruginosa (blue-green algae)): &gt; 640 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 hrs</td>
</tr>
<tr>
<td></td>
<td>Method: FDA 4.01</td>
</tr>
<tr>
<td></td>
<td>NOEC (Microcystis aeruginosa (blue-green algae)): 330 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 hrs</td>
</tr>
<tr>
<td></td>
<td>Method: FDA 4.01</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

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>3177577-00007</td>
<td>23.03.2020</td>
<td>18.09.2018</td>
</tr>
</tbody>
</table>

**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 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
## SAFETY DATA SHEET

### Ezetimibe / Rosuvastatin Formulation

**Version**: 1.6  
**Revision Date**: 10.10.2020  
**SDS Number**: 3177577-00007  
**Date of last issue**: 23.03.2020  
**Date of first issue**: 18.09.2018

<table>
<thead>
<tr>
<th>Exper. time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>48 h</td>
<td>DIN 38412</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates**

| EL50 (Daphnia magna (Water flea)) | > 1 mg/l  
| Exposure time: 47 h |  
| Test substance: Water Accommodated Fraction  

Remarks: Based on data from similar materials  
No toxicity at the limit of solubility.

**Toxicity to algae/aquatic plants**

| EL50 (Pseudokirchneriella subcapitata (green algae)) | > 1 mg/l  
| Exposure time: 72 h |  
| Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201 |

Remarks: Based on data from similar materials  
No toxicity at the limit of solubility.

| NOELR (Pseudokirchneriella subcapitata (green algae)) | > 1 mg/l  
| Exposure time: 72 h |  
| Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201 |

Remarks: Based on data from similar materials

**Toxicity to microorganisms**

| EC10 (Pseudomonas putida) | > 100 mg/l  
| Exposure time: 16 h |  
| Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials |

### 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.

Domestic regulation

NOM-002-SCT
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Ezetimibe, Rosuvastatin)
Class : 9
SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills: Not applicable

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA : 8-hour, time-weighted average
NOM-010-STPS-2014 / VLE-PPT : Time weighted average limit value

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 - 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;
SAFETY DATA SHEET

Ezetimibe / Rosuvastatin Formulation

Version 1.6  Revision Date: 10.10.2020  SDS Number: 3177577-00007  Date of last issue: 23.03.2020  Date of first issue: 18.09.2018

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


Revision Date: 10.10.2020

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8