SAFETY DATA SHEET

Ezetimibe / Rosuvastatin Formulation

Version 2.4  
Revision Date: 10/10/2020  
SDS Number: 3177581-00008  
Date of last issue: 03/23/2020  
Date of first issue: 09/18/2018

SECTION 1. IDENTIFICATION

Product name: Ezetimibe / Rosuvastatin Formulation

Manufacturer or supplier’s details

Company name of supplier: Organon & Co.
Address: 30 Hudson Street, 33nd floor
Jersey City, New Jersey, U.S.A 07302
Telephone: 551-430-6000
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 in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

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:
If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
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.
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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 and face protection.

Response:  
P307 + P311 IF exposed: Call a doctor.

Storage:  
P405 Store locked up.

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

Other hazards  
Dust contact with the eyes can lead to mechanical irritation.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

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>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Ezetimibe</td>
<td>163222-33-1</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Rosuvastatin</td>
<td>147098-20-2</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

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.
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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. 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

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.

Conditions for safe storage: Keep in properly labeled 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 Organic peroxides Explosives Gases

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>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
</tbody>
</table>
TWA (total dust) | 15 mg/m³ | OSHA Z-1
| TWA (respirable fraction) | 5 mg/m³ | OSHA Z-1

Ezetimibe 163222-33-1 TWA 25 µg/m³ (OEB 3) Internal
Wipe limit 250 µg/100 cm² Internal

Rosuvastatin 147098-20-2 TWA 20 µg/m³ (OEB 3) Internal
Wipe limit 200 µg/100 cm² Internal

Magnesium stearate 557-04-0 TWA (Inhalable particulate matter) 10 mg/m³ ACGIH
TWA (Respirable particulate matter) 3 mg/m³ ACGIH

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: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection
Material: Chemical-resistant gloves
Remarks: Consider double gloving.

Eye protection
Material: 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.
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
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.

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>
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</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 : No data available</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
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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
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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:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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: 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

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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
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.

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

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**: 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
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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:
### Ezetimibe:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
<th>Exposure Time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish (LC50)</td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (EC50)</td>
<td>&gt; 4 mg/l</td>
<td>48 h</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants (EC50)</td>
<td>&gt; 0.317 mg/l</td>
<td>96 h</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity) NOEC</td>
<td>0.051 mg/l</td>
<td>33 d</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) NOEC</td>
<td>4 mg/l</td>
<td>7 d</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

### Rosuvastatin:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
<th>Exposure Time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish (LC50)</td>
<td>&gt; 1,000 mg/l</td>
<td>96 hrs</td>
<td></td>
</tr>
</tbody>
</table>
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Ezetimibe / Rosuvastatin Formulation

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

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

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

NOEC (Daphnia magna (Water flea)): 0.018 mg/l
Exposure time: 21 Days
Method: OECD Test Guideline 211

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
plants

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)): \( \geq 1.357 \) mg/l
Exposure time: 42 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

NOEC (Ceriodaphnia dubia (water flea)): 0.88 mg/l
Exposure time: 7 d

Toxicity to microorganisms

EC50: 135 mg/l
Exposure time: 3 h

Magnesium stearate:

Toxicity to fish

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

Toxicity to daphnia and other aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 1 mg/l
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)
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Version 2.4 Revision Date: 10/10/2020 SDS Number: 3177581-00008 Date of last issue: 03/23/2020

Date of first issue: 09/18/2018

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**

49 CFR
UN/ID/NA number: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Ezetimibe, Rosuvastatin)
Class: 9
Packing group: III
Labels: CLASS 9
ERG Code: 171
Marine pollutant: yes (Ezetimibe, Rosuvastatin)
Remarks: Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

**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**

**CERCLA Reportable Quantity**
This material does not contain any components with a CERCLA RQ.

**SARA 304 Extremely Hazardous Substances Reportable Quantity**
This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**
This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards**
- Combustible dust
- Carcinogenicity
- Reproductive toxicity
- Specific target organ toxicity (single or repeated exposure)

**SARA 313**
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**US State Regulations**

Pennsylvania Right To Know
Ezetimibe / Rosuvastatin Formulation

D-Glucose, 4-O-β-D-galactopyranosyl-, monohydrate 64044-51-5
D-mannitol 69-65-8
Cellulose 9004-34-6
Hydroxypropyl methylcellulose 9004-65-3
Ezetimibe 163222-33-1
Crocarmellose sodium 74811-65-7

California List of Hazardous Substances
Polyvinyl pyrrolidone 9003-39-8

California Permissible Exposure Limits for Chemical Contaminants
Cellulose 9004-34-6
Magnesium stearate 557-04-0

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

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

- Flammability
- Health
- Instability
- Special hazard

HMIS® IV:

- HEALTH
- FLAMMABILITY
- PHYSICAL HAZARD

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- NIOSH REL: USA. NIOSH Recommended Exposure Limits
- OSHA Z-1: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- ACGIH / TWA: 8-hour, time-weighted average
- NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; IECCSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; ILO - 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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


Revision Date : 10/10/2020

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.