

# 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

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### 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


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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Skin irritation : Category 3  
Carcinogenicity : Category 1B  
Reproductive toxicity : Category 1B  
Specific target organ toxicity : Category 1 (Liver, Kidney, muscle)  
- single exposure (Oral)  
Specific target organ toxicity : Category 1 (Eye)  
- repeated exposure (Oral)

#### 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.

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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**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 10 -< 20
Ezetimibe	163222-33-1	>= 5 -< 10
Rosuvastatin	147098-20-2	>= 1 -< 5
Sodium n-dodecyl sulfate	151-21-3	>= 1 -< 3
Magnesium stearate	557-04-0	>= 1 -< 5

**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.

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delayed : May damage fertility. May damage the unborn child.  
Causes damage to organs if swallowed.  
Causes 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. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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 (NO<sub>x</sub>)  
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

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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.

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**SECTION 7. HANDLING AND STORAGE**

- |                             |   |  |
|-----------------------------|---|--|
| Technical measures          | : | Static electricity may accumulate and ignite suspended dust causing an explosion.<br>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.<br>Do not breathe dust.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>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.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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 labeled containers.<br>Store locked up.<br>Keep tightly closed.<br>Store in accordance with the particular national regulations.  |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Organic peroxides<br>Explosives<br>Gases  |

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**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Ingredients with workplace control parameters**

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

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Use appropriate degowning techniques to remove potentially contaminated clothing.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	white to off-white
Odor	:	No data available
Odor 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
Vapor pressure	:	Not applicable
Relative vapor 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
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable

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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

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**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.

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**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
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**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
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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



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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

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**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

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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

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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

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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

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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 :  $\geq 9,000$  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

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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  
 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

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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



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- 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

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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

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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  
 Method: Directive 67/548/EEC, Annex V, C.2.  
 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)

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**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

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**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

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Packing group : III  
Labels : 9

**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**

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- : Time weighted average limit value  
PPT

AllC - 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



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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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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.

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