

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Ezetimibe / Rosuvastatin Formulation

Version 1.7      Revision Date: 09.04.2021      SDS Number: 3178918-00008      Date of last issue: 10.10.2020  
Date of first issue: 18.09.2018

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

#### 1.1 Product identifier

Trade name : Ezetimibe / Rosuvastatin Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Pharmaceutical

#### 1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.  
Shotton Lane  
NE23 3JU Cramlington NU - Great Britain

Telephone : 44 1 670 59 30 00

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

#### 1.4 Emergency telephone number

215-631-6999

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Carcinogenicity, Category 1B	H350: May cause cancer.
Reproductive toxicity, Category 1B	H360FD: May damage fertility. May damage the unborn child.
Specific target organ toxicity - single exposure, Category 2	H371: May cause damage to organs.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 2	H411: Toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H350 May cause cancer.  
H360FD May damage fertility. May damage the unborn child.

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H371    May cause damage to organs.  
H373    May cause damage to organs through prolonged or repeated exposure.  
H411    Toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**

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

**Response:**

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

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

Rosuvastatin

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Dust contact with the eyes can lead to mechanical irritation.

May form explosive dust-air mixture during processing, handling or other means.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Ezetimibe	163222-33-1	Aquatic Chronic 1; H410  M-Factor (Chronic aquatic toxicity): 1	>= 2.5 - < 10
Rosuvastatin	147098-20-2	Carc. 1B; H350 Repr. 1B; H360FD STOT SE 1; H370 (Liver, Kidney, muscle) STOT RE 1; H372 (Eye) Aquatic Chronic 1; H410	>= 2.5 - < 10

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		M-Factor (Chronic aquatic toxicity): 1	
Sodium n-dodecyl sulfate	151-21-3 205-788-1	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Aquatic Chronic 3; H412	$\geq 1 - < 2.5$

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.  
Never give anything by mouth to an unconscious person.

#### 4.2 Most important symptoms and effects, both acute and delayed

- Risks : May cause cancer.  
May damage fertility. May damage the unborn child.  
May cause damage to organs.  
May cause damage to organs through prolonged or repeated exposure.

Dust contact with the eyes can lead to mechanical irritation.

#### 4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

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### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

#### 5.2 Special hazards arising from the substance or mixture

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>)  
Sulphur oxides  
Metal oxides

#### 5.3 Advice for firefighters

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

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

#### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

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### 6.3 Methods and material for containment and cleaning up

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

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.  
Do not breathe dust.  
Do not swallow.  
Avoid contact with eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

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

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Cellulose	9004-34-6	TWA (inhalable dust)	10 mg/m <sup>3</sup>	GB EH40
		Further information: For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols., The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m <sup>-3</sup> 8-hour TWA of inhalable dust or 4 mg.m <sup>-3</sup> 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits., Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed 'inhalable' and 'respirable'. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4., Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with.		
		TWA (Respirable dust)	4 mg/m <sup>3</sup>	GB EH40
		Further information: For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols., The COSHH definition of a substance		

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	hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m <sup>-3</sup> 8-hour TWA of inhalable dust or 4 mg.m <sup>-3</sup> 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits., Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed 'inhalable' and 'respirable'. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4., Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with.			
		STEL (inhalable dust)	20 mg/m <sup>3</sup>	GB EH40
	Further information: For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols., The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m <sup>-3</sup> 8-hour TWA of inhalable dust or 4 mg.m <sup>-3</sup> 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits., Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed 'inhalable' and 'respirable'. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4., Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with.			
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

### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium n-dodecyl sulfate	Workers	Inhalation	Long-term systemic effects	285 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	4060 mg/kg bw/day

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	Consumers	Inhalation	Long-term systemic effects	85 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	2440 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	24 mg/kg bw/day

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Sodium n-dodecyl sulfate	Fresh water	0.176 mg/l
	Marine water	0.018 mg/l
	Sewage treatment plant	1.35 mg/l
	Fresh water sediment	6.97 mg/kg dry weight (d.w.)
	Marine sediment	0.697 mg/kg dry weight (d.w.)
	Soil	1.29 mg/kg dry weight (d.w.)

## 8.2 Exposure controls

### Engineering measures

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

### Personal protective equipment

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

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Skin and body protection : Work uniform or laboratory coat.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.

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

Equipment should conform to BS EN 143

Filter type : Particulates type (P)



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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

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

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### 9.2 Other information

Molecular weight : No data available  
Particle size : No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

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

### 10.4 Conditions to avoid

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

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

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: > 2,000 mg/kg  
Method: Calculation method

#### Components:

##### 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

### **Skin corrosion/irritation**

Not classified based on available information.

### **Components:**

#### **Ezetimibe:**

Species : Rabbit  
Result : No skin irritation

#### **Sodium n-dodecyl sulfate:**

Species : Rabbit  
Result : Skin irritation

### **Serious eye damage/eye irritation**

Not classified based on available information.

### **Components:**

#### **Ezetimibe:**

Species : Rabbit  
Result : No eye irritation

#### **Sodium n-dodecyl sulfate:**

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : Irreversible effects on the eye

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### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### Ezetimibe:

Test Type : Maximisation Test  
Species : Guinea pig  
Result : negative

##### Sodium n-dodecyl sulfate:

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative  
Remarks : Based on data from similar materials

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### Ezetimibe:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Metabolic activation: with and without metabolic activation  
Result: negative

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

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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

### **Carcinogenicity**

May cause cancer.

### **Components:**

#### **Ezetimibe:**

Species : Rat, female  
Application Route : oral (feed)  
Exposure time : 104 weeks  
Result : negative

Species : Rat, male  
Application Route : oral (feed)  
Exposure time : 104 weeks  
Result : negative

Species : Mouse  
Application Route : oral (feed)  
Exposure time : 104 weeks  
Result : negative

#### **Rosuvastatin:**

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

Species : Mouse  
Application Route : Oral  
Exposure time : 107 weeks

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LOAEL : 200 mg/kg body weight  
Result : positive  
Symptoms : liver adenoma, carcinoma  
Target Organs : Liver

### Sodium n-dodecyl sulfate:

Species : Rat  
Application Route : Ingestion  
Exposure time : 2 Years  
Method : OECD Test Guideline 453  
Result : negative  
Remarks : Based on data from similar materials

### Reproductive toxicity

May damage fertility. May damage the unborn child.

### Components:

#### Ezetimibe:

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

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

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

#### Rosuvastatin:

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

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

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

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Result: foetal mortality

Test Type: Development

Species: Rabbit

Application Route: Oral

Developmental Toxicity: LOAEL: 3 mg/kg body weight

Result: foetal mortality, Maternal toxicity observed.

Reproductive toxicity - Assessment : May damage fertility. May damage the unborn child.

### **Sodium n-dodecyl sulfate:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 416  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

### **STOT - single exposure**

May cause damage to organs.

#### **Components:**

##### **Rosuvastatin:**

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

### **STOT - repeated exposure**

May cause damage to organs through prolonged or repeated exposure.

#### **Components:**

##### **Rosuvastatin:**

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

### **Repeated dose toxicity**

#### **Components:**

##### **Ezetimibe:**

Species : Dog  
NOAEL : 1,000 mg/kg

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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 yr  
Remarks : No significant adverse effects were reported

### **Rosuvastatin:**

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

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

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

Species : Dog  
LOAEL : 90 mg/kg  
Application Route : Oral  
Exposure time : 4 Weeks  
Target Organs : eye - retina  
Symptoms : Eye disease



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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

### Aspiration toxicity

Not classified based on available information.

### Components:

#### Ezetimibe:

Not applicable

### Experience with human exposure

### Components:

#### Ezetimibe:

Ingestion : Symptoms: Headache, Nausea, Vomiting, Diarrhoea, flatulence, muscle pain, upper respiratory tract infection, Back pain, joint pain

#### Rosuvastatin:

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

## SECTION 12: Ecological information

### 12.1 Toxicity

### Components:

#### Ezetimibe:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 0.125 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 4 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: No toxicity at the limit of solubility

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- Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.317 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility
- NOEC (Pseudokirchneriella subcapitata (green algae)): 0.317 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility
- Toxicity to 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
- Toxicity to fish (Chronic toxicity) : NOEC: 0.051 mg/l  
Exposure time: 33 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210
- NOEC: 4 mg/l  
Exposure time: 7 d  
Species: Cyprinodon variegatus (sheepshead minnow)  
Remarks: No toxicity at the limit of solubility
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0.282 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Remarks: No toxicity at the limit of solubility
- M-Factor (Chronic aquatic toxicity) : 1
- Rosuvastatin:**
- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l  
Exposure time: 96 hrs  
Method: FDA 4.11
- LC50 (Lepomis macrochirus (Bluegill sunfish)): > 1,000 mg/l  
Exposure time: 96 hrs  
Method: FDA 4.11
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 63 mg/l  
Exposure time: 48 hrs

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Method: OECD Test Guideline 202

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

NOEC (Microcystis aeruginosa (blue-green algae)): 330 mg/l  
Exposure time: 96 hrs  
Method: FDA 4.01

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

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

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

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

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

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

M-Factor (Chronic aquatic toxicity) : 1

### Sodium n-dodecyl sulfate:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 29 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l  
Exposure time: 72 h

NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l

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Exposure time: 72 h

Toxicity to microorganisms : EC50 : 135 mg/l  
Exposure time: 3 h

Toxicity to fish (Chronic toxicity) : NOEC:  $\geq$  1.357 mg/l  
Exposure time: 42 d  
Species: Pimephales promelas (fathead minnow)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0.88 mg/l  
Exposure time: 7 d  
Species: Ceriodaphnia dubia (water flea)

### 12.2 Persistence and degradability

#### Components:

##### **Ezetimibe:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 6.8 %  
Exposure time: 28 d

Stability in water : Hydrolysis: 50 % (4.5 d)  
Method: OECD Test Guideline 111

##### **Rosuvastatin:**

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

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

##### **Sodium n-dodecyl sulfate:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 95 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

### 12.3 Bioaccumulative potential

#### Components:

##### **Ezetimibe:**

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)  
Exposure time: 97 d  
Bioconcentration factor (BCF): 173  
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 4.36

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### **Rosuvastatin:**

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

### **Sodium n-dodecyl sulfate:**

Partition coefficient: n-octanol/water : log Pow: 0.83

## 12.4 Mobility in soil

### Components:

#### **Ezetimibe:**

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

#### **Rosuvastatin:**

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

## 12.5 Results of PBT and vPvB assessment

### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## 12.6 Other adverse effects

### Product:

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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## SECTION 14: Transport information

### 14.1 UN number

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<b>ADN</b>	:	UN 3077
<b>ADR</b>	:	UN 3077
<b>RID</b>	:	UN 3077
<b>IMDG</b>	:	UN 3077
<b>IATA</b>	:	UN 3077

### 14.2 UN proper shipping name

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

### 14.3 Transport hazard class(es)

<b>ADN</b>	:	9
<b>ADR</b>	:	9
<b>RID</b>	:	9
<b>IMDG</b>	:	9
<b>IATA</b>	:	9

### 14.4 Packing group

<b>ADN</b>		
Packing group	:	III
Classification Code	:	M7
Hazard Identification Number	:	90
Labels	:	9
<b>ADR</b>		
Packing group	:	III
Classification Code	:	M7
Hazard Identification Number	:	90
Labels	:	9
Tunnel restriction code	:	(-)
<b>RID</b>		
Packing group	:	III
Classification Code	:	M7
Hazard Identification Number	:	90

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Labels : 9

### IMDG

Packing group : III  
Labels : 9  
EmS Code : F-A, S-F

### IATA (Cargo)

Packing instruction (cargo aircraft) : 956  
Packing instruction (LQ) : Y956  
Packing group : III  
Labels : Miscellaneous

### IATA (Passenger)

Packing instruction (passenger aircraft) : 956  
Packing instruction (LQ) : Y956  
Packing group : III  
Labels : Miscellaneous

## 14.5 Environmental hazards

### ADN

Environmentally hazardous : yes

### ADR

Environmentally hazardous : yes

### RID

Environmentally hazardous : yes

### IMDG

Marine pollutant : yes

### IATA (Passenger)

Environmentally hazardous : yes

### IATA (Cargo)

Environmentally hazardous : yes

## 14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

## 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

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## SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable  
REACH - Candidate List of Substances of Very High : Not applicable

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Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

E2	ENVIRONMENTAL HAZARDS	Quantity 1 200 t	Quantity 2 500 t
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### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS : not determined

DSL : not determined

IECSC : not determined

## 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

### Full text of H-Statements

H302 : Harmful if swallowed.

H315 : Causes skin irritation.

H318 : Causes serious eye damage.

H350 : May cause cancer.

H360FD : May damage fertility. May damage the unborn child.

H370 : Causes damage to organs if swallowed.

H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.

H410 : Very toxic to aquatic life with long lasting effects.

H412 : Harmful to aquatic life with long lasting effects.

### Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Chronic : Long-term (chronic) aquatic hazard



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Carc.	: Carcinogenicity
Eye Dam.	: Serious eye damage
Repr.	: Reproductive toxicity
Skin Irrit.	: Skin irritation
STOT RE	: Specific target organ toxicity - repeated exposure
STOT SE	: Specific target organ toxicity - single exposure
GB EH40	: UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA	: Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL	: Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - 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; 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; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Further information

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

### Classification of the mixture:

Carc. 1B	H350
Repr. 1B	H360FD
STOT SE 2	H371
STOT RE 2	H373

### Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method

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Aquatic Chronic 2

H411

Calculation method

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