# SAFETY DATA SHEET

# Ezetimibe / Rosuvastatin Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
|---|---|---|---|
| 2.1 | 30.09.2023 | 3177582-00014 | 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

Recommended restrictions on use : Not applicable

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

Company : Organon & Co.
30 Hudson Street, 33nd floor
07302 Jersey City, New Jersey, U.S.A

Telephone : +1-551-430-6000

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

### 1.4 Emergency telephone number

+1-215-631-6999

## 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.
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.<br>EC-No.<br>Index-No.<br>Registration number | Classification | Concentration (% w/w) |
|---|---|---|---|
| Ezetimibe | 163222-33-1 | Aquatic Chronic 1; H410<br>---<br>M-Factor (Chronic aquatic toxicity): 1 | >= 2,5 - < 10 |
| Rosuvastatin | 147098-20-2 | Carc. 1B; H350<br>Repr. 1B; H360FD<br>STOT SE 1; H370 (Liver, Kidney, muscle)<br>STOT RE 1; H372 (Eye) | >= 2,5 - < 10 |

| | | | |
|---|---|---|---|
| | | Aquatic Chronic 1; H410<br><br>M-Factor (Chronic aquatic toxicity): 1 | |
| Sodium n-dodecyl sulfate | 151-21-3<br>205-788-1 | Acute Tox. 4; H302<br>Skin Irrit. 2; H315<br>Eye Dam. 1; H318<br>Aquatic Chronic 3; H412 | >= 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.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
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 (NOx)
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.

### 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.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>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.<br>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.<br>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.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

| | | |
|---|---|---|
| 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. When using do not eat, drink or smoke. 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. |

### 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
Self-reactive substances and mixtures
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 | OEL-RL | 10 mg/m3 | ZA OEL |
| | Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents | | | |
| 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 |

**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/m3 |
| | Workers | Skin contact | Long-term systemic effects | 4060 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 85 mg/m3 |
| | 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/face 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.

Filter type : Particulates type (P)

## 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. |
| 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. |

### 9.2 Other information

| | | |
|---|---|---|
| Flammability (liquids) | : | No data available |
| Molecular weight | : | No data available |
| Particle size | : | No data available |

## 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, han- |

dling 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.

## 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

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<br>Method: OECD Test Guideline 401 |
| Acute dermal toxicity | : | LD50 (Rat): > 2.000 mg/kg<br>Method: OECD Test Guideline 402<br>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 |

**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

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 |
| 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
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 |
| 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 |
| 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

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 tox- : NOEC: 0,051 mg/l

| | | |
|---|---|---|
| icity) | | Exposure time: 33 d<br>Species: Pimephales promelas (fathead minnow)<br>Method: OECD Test Guideline 210<br><br>NOEC: 4 mg/l<br>Exposure time: 7 d<br>Species: Cyprinodon variegatus (sheepshead minnow)<br>Remarks: No toxicity at the limit of solubility |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 0,282 mg/l<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea)<br>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<br>Exposure time: 96 hrs<br>Method: FDA 4.11<br><br>LC50 (Lepomis macrochirus (Bluegill sunfish)): > 1.000 mg/l<br>Exposure time: 96 hrs<br>Method: FDA 4.11 |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 63 mg/l<br>Exposure time: 48 hrs<br>Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | EC50 (Microcystis aeruginosa (blue-green algae)): > 640 mg/l<br>Exposure time: 96 hrs<br>Method: FDA 4.01<br><br>NOEC (Microcystis aeruginosa (blue-green algae)): 330 mg/l<br>Exposure time: 96 hrs<br>Method: FDA 4.01<br><br>EC50 (Pseudokirchneriella subcapitata (green algae)): > 800 mg/l<br>Exposure time: 96 hrs<br>Method: FDA 4.01<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 350 mg/l<br>Exposure time: 96 hrs<br>Method: FDA 4.01 |
| Toxicity to microorganisms | : | EC50 : > 100 mg/l<br>Exposure time: 3 hrs<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209<br><br>NOEC : 100 mg/l<br>Exposure time: 3 hrs |

| | | |
|---|---|---|
| | | Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209 |
| Toxicity to fish (Chronic toxicity) | : | NOEC: 1 mg/l<br>Exposure time: 32 Days<br>Species: Pimephales promelas (fathead minnow)<br>Method: OECD Test Guideline 210 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 0,018 mg/l<br>Exposure time: 21 Days<br>Species: Daphnia magna (Water flea)<br>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<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Ceriodaphnia dubia (water flea)): 5,55 mg/l<br>Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | ErC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l<br>Exposure time: 72 h |
| | | NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l<br>Exposure time: 72 h |
| Toxicity to microorganisms | : | EC50 : 135 mg/l<br>Exposure time: 3 h |
| Toxicity to fish (Chronic toxicity) | : | NOEC: >= 1,357 mg/l<br>Exposure time: 42 d<br>Species: Pimephales promelas (fathead minnow) |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 0,88 mg/l<br>Exposure time: 7 d<br>Species: Ceriodaphnia dubia (water flea) |

### 12.2 Persistence and degradability

**Components:**

**Ezetimibe:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 6,8 %<br>Exposure time: 28 d |
| Stability in water | : | Hydrolysis: 50 %(4,5 d)<br>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

**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. |

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

| | | |
|---|---|---|
| Product | : | Dispose of in accordance with local regulations.<br>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product. |

## SECTION 14: Transport information

### 14.1 UN number

| | | |
|---|---|---|
| **ADN** | : | UN 3077 |
| **ADR** | : | UN 3077 |
| **RID** | : | UN 3077 |
| **IMDG** | : | UN 3077 |
| **IATA** | : | UN 3077 |

### 14.2 UN proper shipping name

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

### 14.3 Transport hazard class(es)

| | | Class | Subsidiary risks |
|---|---|---|---|
| **ADN** | : | 9 | |
| **ADR** | : | 9 | |
| **RID** | : | 9 | |
| **IMDG** | : | 9 | |
| **IATA** | : | 9 | |

**14.4 Packing group**

**ADN**

| | | |
|---|---|---|
| Packing group | : | III |
| Classification Code | : | M7 |
| Hazard Identification Number | : | 90 |
| Labels | : | 9 |

**ADR**

| | | |
|---|---|---|
| Packing group | : | III |
| Classification Code | : | M7 |
| Hazard Identification Number | : | 90 |
| Labels | : | 9 |
| Tunnel restriction code | : | (-) |

**RID**

| | | |
|---|---|---|
| Packing group | : | III |
| Classification Code | : | M7 |
| Hazard Identification Number | : | 90 |
| 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.

## SECTION 15: Regulatory information

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

**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 |
| 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 |
| ZA OEL | : | South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits |
| ZA OEL / OEL-RL | : | Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts) |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - 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; TECI - Thailand Existing Chemicals 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

**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:** | | **Classification procedure:** |
|---|---|---|
| Carc. 1B | H350 | Calculation method |
| Repr. 1B | H360FD | Calculation method |

| | | |
|---|---|---|
| STOT SE 2 | H371 | Calculation method |
| STOT RE 2 | H373 | Calculation method |
| Aquatic Chronic 2 | H411 | Calculation method |

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.

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