# SAFETY DATA SHEET

## Ezetimibe / Rosuvastatin Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 23.03.2020 |
|---|---|---|---|
| 1.6 | 10.10.2020 | 3177579-00007 | Date of first issue: 18.09.2018 |

### Section 1: Identification

Product name : Ezetimibe / Rosuvastatin Formulation

**Manufacturer or supplier's details**

Company : Organon & Co.

Address : 30 Hudson Street, 33nd floor
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical

### Section 2: Hazard identification

**GHS Classification**

Carcinogenicity : Category 1B

Reproductive toxicity : Category 1B

Specific target organ toxicity - single exposure (Oral) : Category 2 (Liver, Kidney, muscle)

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Eye)

**GHS label elements**

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 (Liver, Kidney, muscle) if swallowed.
H373 May cause 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.
P281 Use personal protective equipment as required.

**Response:**

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards which do not result in classification**

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 -< 30 |
| Ezetimibe | 163222-33-1 | < 10 |
| Rosuvastatin | 147098-20-2 | >= 1 -< 10 |
| Sodium n-dodecyl sulfate | 151-21-3 | >= 1 -< 3 |
| Magnesium stearate | 557-04-0 | < 10 |

## Section 4: First-aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and : May cause cancer.
May damage fertility. May damage the unborn child.

| | | |
|---|---|---|
| delayed | | May cause damage to organs if swallowed.<br>May cause damage to organs through prolonged or repeated exposure if swallowed.<br>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<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>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.<br>Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides<br>Fluorine compounds<br>Nitrogen oxides (NOx)<br>Sulphur oxides<br>Metal oxides |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |
| Hazchem Code | : | 2Z |

## Section 6: Accidental release measures

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>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.<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 surfac- |

es, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

## Section 7: Handling and storage

| | | |
|---|---|---|
| Technical measures | : | Static electricity may accumulate and ignite suspended dust causing an explosion.<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 labelled 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 |

## Section 8: Exposure controls/personal protection

### Components with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|---|---|---|---|
| Cellulose | 9004-34-6 | WES-TWA | 10 mg/m3 | NZ OEL |
| | | TWA | 10 mg/m3 | ACGIH |
| Ezetimibe | 163222-33-1 | TWA | 25 µg/m3 (OEB 3) | Internal |
| | | Wipe limit | 250 µg/100 cm² | Internal |
| Rosuvastatin | 147098-20-2 | TWA | 20 µg/m3 (OEB 3) | Internal |
| | | Wipe limit | 200 µg/100 cm² | Internal |
| Magnesium stearate | 557-04-0 | WES-TWA | 10 mg/m3 | NZ OEL |
| | | TWA (Inhalable particulate matter) | 10 mg/m3 | ACGIH |
| | | TWA (Respirable particulate matter) | 3 mg/m3 | ACGIH |

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

**Personal protective equipment**

Respiratory protection : 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.
Use appropriate degowning techniques to remove potentially contaminated clothing.

## Section 9: 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. |
| Molecular weight | : | No data available |

| | | |
|---|---|---|
| Particle size | : | No data available |

## 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.<br>Can react with strong oxidizing agents. |
| Conditions to avoid | : | Heat, flames and sparks.<br>Avoid dust formation. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

## Section 11: Toxicological information

Exposure routes : 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:**

**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

LD50 (Dog): > 3,000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : LD50 (Rat): > 2,000 mg/kg
Application Route: Intraperitoneal

LD50 (Mouse): > 1,000 - < 2,000 mg/kg
Application Route: Intraperitoneal

**Rosuvastatin:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Target Organs: Liver, Stomach, muscle, Kidney

**Sodium n-dodecyl sulfate:**

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg
Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials

**Magnesium stearate:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Remarks: Based on data from similar materials

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**Ezetimibe:**

Species : Rabbit
Result : No skin irritation

**Sodium n-dodecyl sulfate:**

Species : Rabbit
Result : Skin irritation

**Magnesium stearate:**

Species : Rabbit
Result : No skin irritation
Remarks : Based on data from similar materials

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**Ezetimibe:**

Species : Rabbit

Result : No eye irritation

**Sodium n-dodecyl sulfate:**

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

**Magnesium stearate:**

Species : Rabbit
Result : No eye irritation
Remarks : Based on data from similar materials

**Respiratory or skin 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

**Magnesium stearate:**

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
Remarks : Based on data from similar materials

**Chronic toxicity**

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**Cellulose:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

**Ezetimibe:**

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

Test Type: Chromosomal aberration
Test system: Human lymphocytes
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

**Rosuvastatin:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Test system: Escherichia coli
Result: negative

Test Type: Chromosomal aberration
Test system: Chinese hamster lung cells
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Ingestion
Result: negative

**Sodium n-dodecyl sulfate:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Mouse
Application Route: Ingestion
Result: negative

**Magnesium stearate:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

**Carcinogenicity**

May cause cancer.

**Components:**

**Cellulose:**

| | | |
|---|---|---|
| Species | : | Rat |
| Application Route | : | Ingestion |
| Exposure time | : | 72 weeks |
| Result | : | negative |

**Ezetimibe:**

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

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

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

**Rosuvastatin:**

| | | |
|---|---|---|
| Species | : | Rat |
| Application Route | : | Oral |
| Exposure time | : | 104 weeks |
| LOAEL | : | 80 mg/kg body weight |
| Result | : | positive |
| Symptoms | : | 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:**

**Cellulose:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
| Effects on foetal development | : | Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

**Ezetimibe:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Fertility/early embryonic development<br>Species: Rat, male and female<br>Fertility: NOAEL: > 1,000 mg/kg body weight<br>Result: No effects on fertility, No fetotoxicity |
| Effects on foetal development | : | Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: > 1,000 mg/kg body weight<br>Result: No adverse effects<br><br>Test Type: Development<br>Species: Rabbit<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: > 1,000 mg/kg body weight<br>Result: No adverse effects |

**Rosuvastatin:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Fertility<br>Species: Rat<br>Application Route: Oral<br>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

**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 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 (Liver, Kidney, muscle) if swallowed.

**Components:**

**Rosuvastatin:**

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

**STOT - repeated exposure**

May cause damage to organs (Eye) through prolonged or repeated exposure if swallowed.

**Components:**

**Rosuvastatin:**

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

**Repeated dose toxicity**

**Components:**

**Cellulose:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | >= 9,000 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |

**Ezetimibe:**

| | | |
|---|---|---|
| Species | : | Dog |
| NOAEL | : | 1,000 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 90 d |
| Remarks | : | No significant adverse effects were reported |

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 1,500 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 90 d |
| Remarks | : | No significant adverse effects were reported |

| | | |
|---|---|---|
| Species | : | Mouse |
| NOAEL | : | 500 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 90 d |
| Remarks | : | No significant adverse effects were reported |

| | | |
|---|---|---|
| Species | : | Dog |
| NOAEL | : | 300 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 1 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 |

**Magnesium stearate:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | > 100 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |
| Remarks | : | Based on data from similar materials |

**Aspiration toxicity**

Not classified based on available information.

**Components:**

**Ezetimibe:**
Not applicable

**Experience with human exposure**

**Components:**

**Ezetimibe:**

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

**Rosuvastatin:**

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

## Section 12: Ecological information

**Ecotoxicity**

**Components:**

**Cellulose:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l<br>Exposure time: 48 h<br>Remarks: Based on data from similar materials |

**Ezetimibe:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): > 0.125 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203<br>Remarks: No toxicity at the limit of solubility |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 4 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202<br>Remarks: No toxicity at the limit of solubility |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.317 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility<br><br>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

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

| | | |
|---|---|---|
| | | NOEC (Pseudokirchneriella subcapitata (green algae)): 350 mg/l<br>Exposure time: 96 hrs<br>Method: FDA 4.01 |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Pimephales promelas (fathead minnow)): 1 mg/l<br>Exposure time: 32 Days<br>Method: OECD Test Guideline 210 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 0.018 mg/l<br>Exposure time: 21 Days<br>Method: OECD Test Guideline 211 |
| Toxicity to microorganisms | : | EC50: > 100 mg/l<br>Exposure time: 3 hrs<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209 |
| | | NOEC: 100 mg/l<br>Exposure time: 3 hrs<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209 |

**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 fish (Chronic toxicity) | : | NOEC (Pimephales promelas (fathead minnow)): >= 1.357 mg/l<br>Exposure time: 42 d |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Ceriodaphnia dubia (water flea)): 0.88 mg/l<br>Exposure time: 7 d |
| Toxicity to microorganisms | : | EC50: 135 mg/l<br>Exposure time: 3 h |

**Magnesium stearate:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l<br>Exposure time: 48 h<br>Method: DIN 38412<br>Remarks: Based on data from similar materials |
| Toxicity to daphnia and other | : | EL50 (Daphnia magna (Water flea)): > 1 mg/l |

| | | |
|---|---|---|
| aquatic invertebrates | | Exposure time: 47 h<br>Test substance: Water Accommodated Fraction<br>Method: Directive 67/548/EEC, Annex V, C.2.<br>Remarks: Based on data from similar materials<br>No toxicity at the limit of solubility |
| Toxicity to algae/aquatic plants | : | EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l<br>Exposure time: 72 h<br>Test substance: Water Accommodated Fraction<br>Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials<br>No toxicity at the limit of solubility<br><br>NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l<br>Exposure time: 72 h<br>Test substance: Water Accommodated Fraction<br>Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials |
| Toxicity to microorganisms | : | EC10 (Pseudomonas putida): > 100 mg/l<br>Exposure time: 16 h<br>Test substance: Water Accommodated Fraction<br>Remarks: Based on data from similar materials |

**Persistence and degradability**

**Components:**

**Cellulose:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Readily biodegradable. |

**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 %<br>Exposure time: 28 Days<br>Method: OECD Test Guideline 301F<br>Remarks: Not inherently biodegradable. |
| Stability in water | : | Hydrolysis: < 10 %(5 Days) |

**Sodium n-dodecyl sulfate:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 95 % |

Exposure time: 28 d
Method: OECD Test Guideline 301B

**Magnesium stearate:**

Biodegradability : Result: Not biodegradable
Remarks: Based on data from similar materials

**Bioaccumulative potential**

**Components:**

**Ezetimibe:**

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

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

**Rosuvastatin:**

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

**Sodium n-dodecyl sulfate:**

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

**Magnesium stearate:**

Partition coefficient: n-octanol/water : log Pow: > 4

**Mobility in soil**

**Components:**

**Ezetimibe:**

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

**Rosuvastatin:**

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

**Other adverse effects**

No data available

## Section 13: Disposal considerations

**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

## Section 14: Transport information

### International Regulations

**UNRTDG**

| | | |
|---|---|---|
| UN number | : | UN 3077 |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe, Rosuvastatin) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |

**IATA-DGR**

| | | |
|---|---|---|
| UN/ID No. | : | UN 3077 |
| Proper shipping name | : | Environmentally hazardous substance, solid, n.o.s. (Ezetimibe, Rosuvastatin) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | Miscellaneous |
| Packing instruction (cargo aircraft) | : | 956 |
| Packing instruction (passenger aircraft) | : | 956 |
| Environmentally hazardous | : | yes |

**IMDG-Code**

| | | |
|---|---|---|
| UN number | : | UN 3077 |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe, Rosuvastatin) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| EmS Code | : | F-A, S-F |
| Marine pollutant | : | yes |

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

### National Regulations

**NZS 5433**

| | | |
|---|---|---|
| UN number | : | UN 3077 |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe, Rosuvastatin) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| Hazchem Code | : | 2Z |

**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**

**HSNO Approval Number**

HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

**HSW Controls**

Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

| | | |
|---|---|---|
| AICS | : | not determined |
| DSL | : | not determined |
| IECSC | : | not determined |

## Section 16: Other information

**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/ |
| Date format | : | dd.mm.yyyy |

**Full text of other abbreviations**

| | | |
|---|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| NZ OEL | : | New Zealand. Workplace Exposure Standards for Atmospheric Contaminants |
| ACGIH / TWA | : | 8-hour, time-weighted average |
| NZ OEL / WES-TWA | : | Workplace Exposure Standard - Time Weighted average |

AIIC - 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 Chemi-

cal 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; 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

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.

NZ / EN