SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

Public

ORGANON

Ezetimibe / Rosuvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
2.2	06.04.2024	3178946-00015	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.

Ecological information: 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.

Toxicological information: 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.

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.	Classification	Concentration

	EC-No. Index-No. Registration number		(% 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 ——————— M-Factor (Chronic aquatic toxicity): 1	>= 2,5 - < 10
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 ——————— specific concentration limit Eye Irrit. 2; H319 10 - < 20 % Eye Dam. 1; H318 >= 20 % ——————— Acute toxicity estimate Acute oral toxicity: 1.200 mg/kg	>= 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.
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.

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.

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

Dust

5 mg/m3
Value type (Form of exposure): TWA (respirable dust)
Basis: FOR-2011-12-06-1358

10 mg/m3
Value type (Form of exposure): TWA (total dust)
Basis: FOR-2011-12-06-1358

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
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. Equipment should conform to NS EN 143
Filter type	:	Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	powder
Colour	:	white to off-white
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
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
Flash point	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	Not applicable
Particle characteristics		
Particle size	:	No data available

9.2 Other information

Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Evaporation rate	:	Not applicable
Molecular weight	:	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, 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.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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 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

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

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment	:	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.

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 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	:	NOEC: 0,282 mg/l

aquatic invertebrates (Chronic toxicity)		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 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 Exposure time: 72 h
Toxicity to microorganisms	:	EC50 : 135 mg/l Exposure time: 3 h
Toxicity to fish (Chronic toxicity)	:	NOEC: >= 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

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 Endocrine disrupting properties

Product:

Assessment : 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. 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. Do not dispose of waste into sewer.
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

14.1 UN number or ID 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. (Ezetimibe, Rosuvastatin)
ADR	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe, Rosuvastatin)
RID	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe, Rosuvastatin)
IMDG	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe, Rosuvastatin)
IATA	:	Environmentally hazardous substance, solid, n.o.s. (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 Maritime transport in bulk according to IMO instruments

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	:	Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
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 (EU) 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.

		Quantity 1	Quantity 2
E2	ENVIRONMENTAL HAZARDS	200 t	500 t

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.
Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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
FOR-2011-12-06-1358	:	Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / TWA	:	Long term exposure limit

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.

NO / EN