

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Ezetimibe / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9371341-00007	Date of first issue: 27.08.2021

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

1.1 Product identifier

Trade name : Ezetimibe / Simvastatin Formulation

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

Use of the Sub-
stance/Mixture : Pharmaceutical

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

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

Telephone : +44 1 670 59 32 05

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) as amended by GB-CLP Regulation, UK
SI 2019/720, and UK SI 2020/1567)**

Skin irritation, Category 2	H315: Causes skin irritation.
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through pro- longed or repeated exposure.
Long-term (chronic) aquatic hazard, Cat- egory 2	H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI
2019/720, and UK SI 2020/1567)**

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Ezetimibe / Simvastatin Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9371341-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H315 Causes skin irritation. H317 May cause an allergic skin reaction. H372 Causes damage to organs through prolonged or repeated exposure. H411 Toxic to aquatic life with long lasting effects.
Precautionary statements	:	Prevention: P260 Do not breathe dust. P264 Wash skin thoroughly after handling. P273 Avoid release to the environment. P280 Wear protective gloves. Response: P314 Get medical advice/ attention if you feel unwell. P391 Collect spillage.

Hazardous components which must be listed on the label:
Simvastatin

2.3 Other hazards

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

Dust contact with the eyes can lead to mechanical irritation.

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

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Ezetimibe	163222-33-1	Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 1	>= 10 - < 20
Simvastatin	79902-63-9	Skin Irrit. 2; H315 Skin Sens. 1; H317 STOT RE 1; H372 (Liver, muscle,	>= 10 - < 20

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ezetimibe / Simvastatin Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9371341-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

		optic nerve, Eye) Aquatic Chronic 2; H411	
Substances with a workplace exposure limit :			
Cellulose	9004-34-6 232-674-9		>= 10 - < 20

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 if symptoms occur.
- In case of skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing 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 if symptoms occur.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : Causes skin irritation.
May cause an allergic skin reaction.
Causes 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.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Ezetimibe / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9371341-00007	Date of first issue: 27.08.2021

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
Nitrogen oxides (NO_x)
Fluorine compounds
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.
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Ezetimibe / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9371341-00007	Date of first issue: 27.08.2021

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 : Use only with adequate 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
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. Contaminated work clothing should not be allowed out of the workplace.
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.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Ezetimibe / Simvastatin Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9371341-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. 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 of any kind	10 mg/m ³	Value type (Form of exposure): TWA (Inhalable)
			Basis: GB EH40
		4 mg/m ³	Value type (Form of exposure): TWA (Respirable fraction)
			Basis: GB EH40

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis	
	Cellulose	9004-34-6	TWA (inhalable dust)	10 mg/m ³	GB EH40
			TWA (Respirable dust)	4 mg/m ³	GB EH40
			STEL (inhalable dust)	20 mg/m ³	GB EH40
	Ezetimibe	163222-33-1	TWA	25 µg/m ³ (OEB 3)	Internal
			Wipe limit	250 µg/100 cm ²	Internal
	Simvastatin	79902-63-9	TWA	25 µg/m ³ (OEB 3)	Internal
			Further information: DSEN		
		Wipe limit	250 µg/100 cm ²	Internal	

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.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Ezetimibe / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9371341-00007	Date of first issue: 27.08.2021

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 BS EN 143
Filter type	:	Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	powder
Colour	:	No data available
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	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Upper explosion limit / Upper	:	No data available

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



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Ezetimibe / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9371341-00007	Date of first issue: 27.08.2021

flammability limit

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

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, 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.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ezetimibe / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9371341-00007	Date of first issue: 27.08.2021

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.

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

Simvastatin:

Acute oral toxicity	: LD50 (Rat): 5,000 mg/kg
	LD50 (Mouse): 3,800 mg/kg

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ezetimibe / Simvastatin Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9371341-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

Skin corrosion/irritation

Causes skin irritation.

Components:

Ezetimibe:

Species : Rabbit
Result : No skin irritation

Simvastatin:

Species : Rabbit
Remarks : Moderate skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Ezetimibe:

Species : Rabbit
Result : No eye irritation

Simvastatin:

Species : Rabbit
Remarks : slight irritation

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

Ezetimibe:

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

Simvastatin:

Assessment : Probability or evidence of skin sensitisation in humans
Result : positive

Germ cell mutagenicity

Not classified based on available information.

Components:

Ezetimibe:

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ezetimibe / Simvastatin Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9371341-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

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

Simvastatin:

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

Test Type: Alkaline elution assay
Result: negative

Test Type: Chromosomal aberration
Result: negative

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

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Germ cell mutagenicity- Assessment : Weight of evidence does not support classification as a germ cell mutagen.

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

Carcinogenicity

Not classified based on available information.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Ezetimibe / Simvastatin Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9371341-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

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

Simvastatin:

Species : Mouse
Application Route : Oral
Exposure time : < 92 weeks
Target Organs : Harderian gland
Tumor Type : Liver, Lungs
Remarks : The significance of these findings for humans is not certain.

Species : Rat
Application Route : Oral
Exposure time : 2 Years
Tumor Type : Liver, Thyroid
Remarks : The significance of these findings for humans is not certain.

Cellulose:

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

Reproductive toxicity

Not classified based on available information.

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Ezetimibe / Simvastatin Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9371341-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

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

Simvastatin:

Effects on fertility : Test Type: Fertility
Species: Rat, male
Application Route: Oral
Fertility: LOAEL: 25 mg/kg body weight

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Embryo-foetal toxicity: NOAEL: 25 mg/kg body weight
Result: No teratogenic effects, No adverse effects

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Embryo-foetal toxicity: NOAEL: 10 mg/kg body weight
Result: No teratogenic effects, No adverse effects

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Embryo-foetal toxicity: LOAEL: 60 mg/kg body weight
Result: Teratogenic potential
Remarks: Based on data from similar materials

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Ezetimibe / Simvastatin Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9371341-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

Components:

Simvastatin:

Target Organs : Liver, muscle, optic nerve, 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

Simvastatin:

Species : Rat
NOAEL : 5 mg/kg
LOAEL : 30 mg/kg
Application Route : Oral
Exposure time : 14 - 104 Weeks
Target Organs : Liver, Testis, Musculo-skeletal system, Eye

Species : Dog
LOAEL : 10 mg/kg
Application Route : Oral
Exposure time : 14 - 104 Weeks
Target Organs : Liver, Testis, Eye

Species : Rabbit
NOAEL : 30 mg/kg

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Ezetimibe / Simvastatin Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9371341-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

|| LOAEL : 50 mg/kg
|| Application Route : Oral
|| Target Organs : Liver, Kidney

Cellulose:

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

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

Simvastatin:

|| Skin contact : Remarks: May produce an allergic reaction.
|| Ingestion : Target Organs: Liver
Symptoms: upper respiratory tract infection, Headache, Abdominal pain, constipation, Nausea
Target Organs: Musculo-skeletal system

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 : EC50 (Pseudokirchneriella subcapitata (green algae)): >

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Ezetimibe / Simvastatin Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9371341-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

plants		0.317 mg/l Exposure time: 96 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility
		NOEC (Pseudokirchneriella subcapitata (green algae)): 0.317 mg/l Exposure time: 96 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility
Toxicity to microorganisms	:	EC50 : > 4.4 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 Remarks: No toxicity at the limit of solubility
		NOEC : 4.4 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 Remarks: No toxicity at the limit of solubility
Toxicity to fish (Chronic toxicity)	:	NOEC: 0.051 mg/l Exposure time: 33 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210
		NOEC: 4 mg/l Exposure time: 7 d Species: Cyprinodon variegatus (sheepshead minnow) Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 0.282 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Remarks: No toxicity at the limit of solubility
M-Factor (Chronic aquatic toxicity)	:	1

Simvastatin:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 2.91 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 3.5 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 25 mg/l Exposure time: 96 h

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Ezetimibe / Simvastatin Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9371341-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

		NOEC (Pseudokirchneriella subcapitata (green algae)): 25 mg/l Exposure time: 96 h
Toxicity to microorganisms	:	EC50 : > 30 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
		NOEC : 21 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

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

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

Simvastatin:

Biodegradability	:	Result: rapidly degradable
Stability in water	:	Hydrolysis: 50 %(3.2 d)

Cellulose:

Biodegradability	:	Result: Readily biodegradable.
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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
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SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Ezetimibe / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9371341-00007	Date of first issue: 27.08.2021

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

Simvastatin:

Partition coefficient: n-octanol/water : log Pow: > 4.07

12.4 Mobility in soil

Components:

Ezetimibe:

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

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 : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

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

ADN : UN 3077
ADR : UN 3077
RID : UN 3077

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ezetimibe / Simvastatin Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9371341-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

IMDG : UN 3077

IATA : UN 3077

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(Ezetimibe, Simvastatin)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(Ezetimibe, Simvastatin)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(Ezetimibe, Simvastatin)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(Ezetimibe, Simvastatin)

IATA : Environmentally hazardous substance, solid, n.o.s.
(Ezetimibe, Simvastatin)

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Ezetimibe / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9371341-00007	Date of first issue: 27.08.2021

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	: Not applicable
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	: Not applicable
The Persistent Organic Pollutants Regulations (retained)	: Not applicable

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



ORGANON

Ezetimibe / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9371341-00007	Date of first issue: 27.08.2021

Regulation (EU) 2019/1021 as amended for Great Britain)

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

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

GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation : Not applicable

Control of Major Accident Hazards Regulations 2015 (COMAH)

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

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

H315 : Causes skin irritation.

H317 : May cause an allergic skin reaction.

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

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

H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Chronic : Long-term (chronic) aquatic hazard

Skin Irrit. : Skin irritation

Skin Sens. : Skin sensitisation

STOT RE : Specific target organ toxicity - repeated exposure

GB EH40 : UK. EH40 WEL - Workplace Exposure Limits

GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)

GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Ezetimibe / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9371341-00007	Date of first issue: 27.08.2021

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:

Skin Irrit. 2	H315
Skin Sens. 1	H317
STOT RE 1	H372
Aquatic Chronic 2	H411

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method

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

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Ezetimibe / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9371341-00007	Date of first issue: 27.08.2021

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.

GB / EN