

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Ezetimibe / Atorvastatin Formulation

Version 2.3      Revision Date: 09/13/2019      SDS Number: 26498-00013      Date of last issue: 24.04.2019  
Date of first issue: 29.10.2014

---

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

#### 1.1 Product identifier

Trade name : Ezetimibe / Atorvastatin Formulation

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

Use of the Sub-stance/Mixture : Pharmaceutical

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

Company : MSD  
Shotton Lane  
NE23 3JU Cramlington NU - Great Britain

Telephone : 44 1 670 59 30 00

Telefax : 908-735-1496

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

1-908-423-6000

---

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

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

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 : Warning

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

Precautionary statements : **Prevention:**

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Ezetimibe / Atorvastatin Formulation

Version 2.3      Revision Date: 09/13/2019      SDS Number: 26498-00013      Date of last issue: 24.04.2019  
Date of first issue: 29.10.2014

P260 Do not breathe dust.  
P273 Avoid release to the environment.

### Response:

P314 Get medical advice/ attention if you feel unwell.  
P391 Collect spillage.

Hazardous components which must be listed on the label:  
Atorvastatin

### 2.3 Other hazards

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
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)
Atorvastatin	134523-03-8	STOT RE2; H373 Aquatic Chronic2; H411	>= 10 - < 20
Ezetimibe	163222-33-1	Aquatic Chronic1; H410  M-Factor (Chronic aquatic toxicity): 1	>= 2,5 - < 10

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 : Wash with water and soap.  
Get medical attention if symptoms occur.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Ezetimibe / Atorvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
2.3	09/13/2019	26498-00013	Date of first issue: 29.10.2014

---

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 : May cause damage to organs through prolonged or repeated exposure.

Contact with dust can cause mechanical irritation or drying of the skin.

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 (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

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

Specific hazards during fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.  
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Ezetimibe / Atorvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
2.3	09/13/2019	26498-00013	Date of first issue: 29.10.2014

---

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 and personal protective equipment recommendations.

#### 6.2 Environmental precautions

Environmental precautions : Discharge into the environment must be avoided.  
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 : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.  
Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Ezetimibe / Atorvastatin Formulation

Version 2.3      Revision Date: 09/13/2019      SDS Number: 26498-00013      Date of last issue: 24.04.2019  
Date of first issue: 29.10.2014

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.  
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 in accordance with the particular national regulations.

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

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Atorvastatin	134523-03-8	TWA	0.05 mg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	0.5 mg/100 cm <sup>2</sup>	Internal
Ezetimibe	163222-33-1	TWA	25 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	250 µg/100 cm <sup>2</sup>	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.  
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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Ezetimibe / Atorvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
2.3	09/13/2019	26498-00013	Date of first issue: 29.10.2014

---

Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection	:	
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	:	Particulates type (P)

---

### SECTION 9: Physical and chemical properties

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

Appearance	:	powder
Colour	:	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	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Ezetimibe / Atorvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
2.3	09/13/2019	26498-00013	Date of first issue: 29.10.2014

---

Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	0,01 g/l
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.
---------------------	---	---

### 10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents
--------------------	---	------------------

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Ezetimibe / Atorvastatin Formulation

Version 2.3      Revision Date: 09/13/2019      SDS Number: 26498-00013      Date of last issue: 24.04.2019  
Date of first issue: 29.10.2014

---

### 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:

###### Atorvastatin:

Acute oral toxicity : LD50 (Rat, male and female): > 5.000 mg/kg  
LD50 (Mouse, male and female): > 5.000 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

##### Skin corrosion/irritation

Not classified based on available information.

##### Components:

###### Atorvastatin:

Species : Rabbit  
Result : No skin irritation

###### Ezetimibe:

Species : Rabbit  
Result : No skin irritation

##### Serious eye damage/eye irritation

Not classified based on available information.



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Ezetimibe / Atorvastatin Formulation

Version 2.3      Revision Date: 09/13/2019      SDS Number: 26498-00013      Date of last issue: 24.04.2019  
Date of first issue: 29.10.2014

---

### Components:

#### **Atorvastatin:**

Species : Rabbit  
Method : Draize Test  
Result : No eye irritation

#### **Ezetimibe:**

Species : Rabbit  
Result : No eye irritation

### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

### Components:

#### **Atorvastatin:**

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative

#### **Ezetimibe:**

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

### **Germ cell mutagenicity**

Not classified based on available information.

### Components:

#### **Atorvastatin:**

Genotoxicity in vitro : Test Type: reverse mutation assay  
Test system: Salmonella typhimurium  
Result: negative

Test Type: reverse mutation assay  
Test system: Escherichia coli  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Test system: Chinese hamster lung cells  
Result: negative

Test Type: sister chromatid exchange assay  
Test system: Chinese hamster lung cells

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Ezetimibe / Atorvastatin Formulation

Version 2.3      Revision Date: 09/13/2019      SDS Number: 26498-00013      Date of last issue: 24.04.2019  
Date of first issue: 29.10.2014

---

Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test  
Species: Mouse  
Cell type: Bone marrow  
Application Route: Oral  
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

### Carcinogenicity

Not classified based on available information.

### Components:

#### Atorvastatin:

Species : Mouse, male and female  
Application Route : oral (gavage)  
Exposure time : 2 Years  
NOAEL : 200 mg/kg body weight  
LOAEL : 400 mg/kg body weight  
Result : negative  
Target Organs : Liver

Species : Rat, female  
Application Route : oral (gavage)  
Exposure time : 2 Years  
LOAEL : 100 mg/kg body weight  
Target Organs : Musculo-skeletal system

#### 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Ezetimibe / Atorvastatin Formulation

Version 2.3      Revision Date: 09/13/2019      SDS Number: 26498-00013      Date of last issue: 24.04.2019  
Date of first issue: 29.10.2014

---

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

### Reproductive toxicity

Not classified based on available information.

### Components:

#### **Atorvastatin:**

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat, female  
Fertility: NOAEL: 225 mg/kg body weight  
Result: No effects on fertility  
  
Test Type: Fertility/early embryonic development  
Species: Rat, male  
Fertility: NOAEL: 175 mg/kg body weight  
Result: No effects on fertility

Effects on foetal development : Species: Rat, female  
Developmental Toxicity: NOAEL: 20 mg/kg body weight  
Result: No teratogenic effects, Embryo-foetal toxicity  
Remarks: Maternal toxicity observed.  
  
Species: Rabbit, female  
Application Route: Oral  
Developmental Toxicity: NOAEL: 100 mg/kg body weight  
Result: No embryo-foetal toxicity

#### **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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Ezetimibe / Atorvastatin Formulation

Version 2.3      Revision Date: 09/13/2019      SDS Number: 26498-00013      Date of last issue: 24.04.2019  
Date of first issue: 29.10.2014

---

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

### Components:

#### Atorvastatin:

Exposure routes : Ingestion  
Target Organs : Liver, muscle  
Assessment : May cause damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

### Components:

#### Atorvastatin:

Species : Rat, male and female  
LOAEL : 70 mg/kg  
Application Route : oral (gavage)  
Exposure time : 52 Weeks  
Target Organs : Liver

Species : Dog  
LOAEL : 10 mg/kg  
Application Route : oral (gavage)  
Exposure time : 104 Weeks  
Target Organs : Liver

#### 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Ezetimibe / Atorvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
2.3	09/13/2019	26498-00013	Date of first issue: 29.10.2014

---

Exposure time : 1 yr  
Remarks : No significant adverse effects were reported

### Aspiration toxicity

Not classified based on available information.

### Components:

#### Ezetimibe:

Not applicable

### Experience with human exposure

### Components:

#### Atorvastatin:

Ingestion : Symptoms: muscle pain, Fatigue, stomach discomfort, Abdominal pain, constipation, flatulence, liver function change

#### Ezetimibe:

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

---

## SECTION 12: Ecological information

### 12.1 Toxicity

### Components:

#### Atorvastatin:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 92 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 200 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 108 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 14 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50 : > 1.000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Ezetimibe / Atorvastatin Formulation

Version 2.3      Revision Date: 09/13/2019      SDS Number: 26498-00013      Date of last issue: 24.04.2019  
Date of first issue: 29.10.2014

---

Toxicity to fish (Chronic toxicity) : NOEC: 0,49 mg/l  
Exposure time: 33 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,2 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

### 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)

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Ezetimibe / Atorvastatin Formulation

Version 2.3      Revision Date: 09/13/2019      SDS Number: 26498-00013      Date of last issue: 24.04.2019  
Date of first issue: 29.10.2014

---

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

### 12.2 Persistence and degradability

#### Components:

##### **Atorvastatin:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 7,7 %  
Exposure time: 28 d  
Method: OECD Test Guideline 314

##### **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

### 12.3 Bioaccumulative potential

#### Components:

##### **Atorvastatin:**

Partition coefficient: n-octanol/water : log Pow: 1,62

##### **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

### 12.4 Mobility in soil

#### Components:

##### **Atorvastatin:**

Distribution among environmental compartments : log Koc: 2,84

##### **Ezetimibe:**

Distribution among environ- : log Koc: 4,35

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Ezetimibe / Atorvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
2.3	09/13/2019	26498-00013	Date of first issue: 29.10.2014

mental compartments

Method: OECD Test Guideline 106

### 12.5 Results of PBT and vPvB assessment

Not relevant

### 12.6 Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

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

## SECTION 14: Transport information

### 14.1 UN number

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

### 14.2 UN proper shipping name

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

### 14.3 Transport hazard class(es)

- |     |   |   |
|-----|---|---|
| ADN | : | 9 |
|-----|---|---|



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Ezetimibe / Atorvastatin Formulation

Version 2.3      Revision Date: 09/13/2019      SDS Number: 26498-00013      Date of last issue: 24.04.2019  
Date of first issue: 29.10.2014

---

**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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Ezetimibe / Atorvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
2.3	09/13/2019	26498-00013	Date of first issue: 29.10.2014

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

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

REACH - Candidate List of Substances of Very High 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 (EC) No 850/2004 on persistent organic pollutants : Not applicable

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

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

E2	ENVIRONMENTAL HAZARDS	Quantity 1 200 t	Quantity 2 500 t
----	-----------------------	---------------------	---------------------

### Other regulations:

Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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

AICS : not determined

DSL : not determined

IECSC : not determined

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Ezetimibe / Atorvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
2.3	09/13/2019	26498-00013	Date of first issue: 29.10.2014

### 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

H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.  
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  
STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; 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; 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Ezetimibe / Atorvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
2.3	09/13/2019	26498-00013	Date of first issue: 29.10.2014

---

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:

STOT RE 2	H373
Aquatic Chronic 2	H411

### Classification procedure:

Calculation method
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