

**Ezetimibe / Atorvastatin Formulation**

Version 4.3      Revision Date: 09/13/2019      SDS Number: 26495-00013      Date of last issue: 24.04.2019  
Date of first issue: 29.10.2014

---

**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Ezetimibe / Atorvastatin Formulation

**Manufacturer or supplier's details**

Company name of supplier : MSD  
Address : Avenida 16 de Septiembre No. 301  
Xaltocan - Xochimilco Mexico 16090  
Telephone : 52 55 57284444  
Telefax : 908-735-1496  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Pharmaceutical

---

**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

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

**GHS label elements**

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H373 May cause damage to organs (Liver, muscle) through prolonged or repeated exposure if swallowed.

Precautionary Statements : **Prevention:**  
P260 Do not breathe dust.  
**Response:**  
P314 Get medical advice/ attention if you feel unwell.  
**Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

**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**

Substance / Mixture : Mixture

**Components**

## Ezetimibe / Atorvastatin Formulation

Version 4.3      Revision Date: 09/13/2019      SDS Number: 26495-00013      Date of last issue: 24.04.2019  
 Date of first issue: 29.10.2014

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 20 -< 30
Atorvastatin	134523-03-8	>= 10 -< 20
Ezetimibe	163222-33-1	>= 1 -< 5
Magnesium stearate	557-04-0	>= 1 -< 5

### SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
 When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
 Get medical attention if symptoms occur.
- In case of skin contact : Wash with water and soap.  
 Get medical attention if symptoms occur.
- 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.
- Most important symptoms and effects, both acute and delayed : May cause damage to organs through prolonged or repeated exposure if swallowed.  
 Contact with dust can cause mechanical irritation or drying of the skin.  
 Dust contact with the eyes can lead to mechanical irritation.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
 Alcohol-resistant foam  
 Carbon dioxide (CO<sub>2</sub>)  
 Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.  
 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
- 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

## Ezetimibe / Atorvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
4.3	09/13/2019	26495-00013	Date of first issue: 29.10.2014

---

Special protective equipment for fire-fighters : so.  
Evacuate area.  
In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

---

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice and personal protective equipment recommendations.

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.

Methods and materials for containment and 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.

---

### SECTION 7. HANDLING AND STORAGE

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  
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.

---

## Ezetimibe / Atorvastatin Formulation

Version 4.3      Revision Date: 09/13/2019      SDS Number: 26495-00013      Date of last issue: 24.04.2019  
 Date of first issue: 29.10.2014

- 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.
- Conditions for safe storage : Keep in properly labeled containers.  
 Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
 Strong oxidizing agents

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010-STPS-2014
		TWA	10 mg/m <sup>3</sup>	ACGIH
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
Magnesium stearate	557-04-0	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010-STPS-2014
		TWA (Inhalable fraction)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable fraction)	3 mg/m <sup>3</sup>	ACGIH

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

#### Personal protective equipment

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Particulates type
- Hand protection
- Material : Chemical-resistant gloves

**Ezetimibe / Atorvastatin Formulation**

Version 4.3      Revision Date: 09/13/2019      SDS Number: 26495-00013      Date of last issue: 24.04.2019  
Date of first issue: 29.10.2014

---

Remarks : Consider double gloving.  
Eye protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.  
Skin and body protection : Work uniform or laboratory coat.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.

---

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : powder  
Color : off-white  
Odor : No data available  
Odor 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.  
Flammability (liquids) : No data available  
Upper explosion limit / Upper flammability limit : No data available  
Lower explosion limit / Lower flammability limit : No data available  
Vapor pressure : No data available  
Relative vapor density : No data available  
Relative density : No data available  
Density : No data available  
Solubility(ies)

**Ezetimibe / Atorvastatin Formulation**

Version 4.3      Revision Date: 09/13/2019      SDS Number: 26495-00013      Date of last issue: 24.04.2019  
Date of first issue: 29.10.2014

---

Water solubility : 0.01 g/l

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

Autoignition 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.

Molecular weight : No data available

Particle size : No data available

---

**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

---

**SECTION 11. TOXICOLOGICAL INFORMATION****Information on likely routes of exposure**

Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Components:****Cellulose:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

---

**Ezetimibe / Atorvastatin Formulation**

Version 4.3      Revision Date: 09/13/2019      SDS Number: 26495-00013      Date of last issue: 24.04.2019  
Date of first issue: 29.10.2014

---

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

**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

**Magnesium stearate:**

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

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

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Atorvastatin:**

Species : Rabbit  
Result : No skin irritation

**Ezetimibe:**

Species : Rabbit  
Result : No skin irritation

**Magnesium stearate:**

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

**Ezetimibe / Atorvastatin Formulation**

Version            Revision Date:            SDS Number:            Date of last issue: 24.04.2019  
4.3                09/13/2019                26495-00013            Date of first issue: 29.10.2014

---

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Atorvastatin:**

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

**Ezetimibe:**

Species                                : Rabbit  
Result                                 : No eye irritation

**Magnesium stearate:**

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

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Atorvastatin:**

Test Type                              : Maximization Test  
Routes of exposure                  : Skin contact  
Species                                : Guinea pig  
Result                                 : negative

**Ezetimibe:**

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

**Magnesium stearate:**

Test Type                              : Maximization Test  
Routes of exposure                  : Skin contact  
Species                                : Guinea pig  
Method                                : OECD Test Guideline 406  
Result                                 : negative  
Remarks                              : Based on data from similar materials

**Germ cell mutagenicity**

Not classified based on available information.



**Ezetimibe / Atorvastatin Formulation**

Version 4.3      Revision Date: 09/13/2019      SDS Number: 26495-00013      Date of last issue: 24.04.2019  
Date of first issue: 29.10.2014

---

**Components:****Cellulose:**

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative
- Test Type: In vitro mammalian cell gene mutation test  
Result: negative
- Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo  
cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

**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  
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

**Ezetimibe / Atorvastatin Formulation**

Version 4.3      Revision Date: 09/13/2019      SDS Number: 26495-00013      Date of last issue: 24.04.2019  
Date of first issue: 29.10.2014

---

**Magnesium stearate:**

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

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

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

**Carcinogenicity**

Not classified based on available information.

**Components:****Cellulose:**

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

**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  
Result : negative

Species : Mouse  
Application Route : oral (feed)

## Ezetimibe / Atorvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
4.3	09/13/2019	26495-00013	Date of first issue: 29.10.2014

---

Exposure time : 104 weeks  
Result : negative

**Reproductive toxicity**

Not classified based on available information.

**Components:****Cellulose:**

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

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

**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 fetal development : Species: Rat, female  
Developmental Toxicity: NOAEL: 20 mg/kg body weight  
Result: No teratogenic effects., Embryo-fetal toxicity.  
Remarks: Maternal toxicity observed.

Species: Rabbit, female  
Application Route: Oral  
Developmental Toxicity: NOAEL: 100 mg/kg body weight  
Result: No embryo-fetal 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 fetal 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

## Ezetimibe / Atorvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
4.3	09/13/2019	26495-00013	Date of first issue: 29.10.2014

---

Species: Rabbit  
 Application Route: Oral  
 Developmental Toxicity: NOAEL: > 1,000 mg/kg body weight  
 Result: No adverse effects.

**Magnesium stearate:**

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
 Species: Rat  
 Application Route: Ingestion  
 Method: OECD Test Guideline 422  
 Result: negative  
 Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative  
 Remarks: Based on data from similar materials

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

May cause damage to organs (Liver, muscle) through prolonged or repeated exposure if swallowed.

**Components:****Atorvastatin:**

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

**Repeated dose toxicity****Components:****Cellulose:**

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

**Atorvastatin:**

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

Species : Dog

**Ezetimibe / Atorvastatin Formulation**

Version 4.3      Revision Date: 09/13/2019      SDS Number: 26495-00013      Date of last issue: 24.04.2019  
Date of first issue: 29.10.2014

---

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

**Magnesium stearate:**

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

**Aspiration toxicity**

Not classified based on available information.

**Components:****Ezetimibe:**

Not applicable

**Experience with human exposure****Components:****Atorvastatin:**

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

## Ezetimibe / Atorvastatin Formulation

Version 4.3      Revision Date: 09/13/2019      SDS Number: 26495-00013      Date of last issue: 24.04.2019  
 Date of first issue: 29.10.2014

### Ezetimibe:

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

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### Cellulose:

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

#### 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 fish (Chronic toxicity) : NOEC (*Pimephales promelas* (fathead minnow)): 0.49 mg/l  
 Exposure time: 33 d  
 Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (*Daphnia magna* (Water flea)): 0.2 mg/l  
 Exposure time: 21 d  
 Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: > 1,000 mg/l  
 Exposure time: 3 h  
 Test Type: Respiration inhibition

#### 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.

## Ezetimibe / Atorvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
4.3	09/13/2019	26495-00013	Date of first issue: 29.10.2014

---

- 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 fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.051 mg/l  
 Exposure time: 33 d  
 Method: OECD Test Guideline 210
- NOEC (Cyprinodon variegatus (sheepshead minnow)): 4 mg/l  
 Exposure time: 7 d  
 Remarks: No toxicity at the limit of solubility.
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.282 mg/l  
 Exposure time: 21 d  
 Remarks: No toxicity at the limit of solubility.
- Toxicity to microorganisms : EC50: > 4.4 mg/l  
 Exposure time: 3 h  
 Test Type: Respiration inhibition  
 Method: OECD Test Guideline 209  
 Remarks: No toxicity at the limit of solubility.
- NOEC: 4.4 mg/l  
 Exposure time: 3 h  
 Test Type: Respiration inhibition  
 Method: OECD Test Guideline 209  
 Remarks: No toxicity at the limit of solubility.
- Magnesium stearate:**
- Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l  
 Exposure time: 48 h  
 Method: DIN 38412  
 Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 1 mg/l  
 Exposure time: 47 h  
 Test substance: Water Accommodated Fraction  
 Method: Directive 67/548/EEC, Annex V, C.2.  
 Remarks: Based on data from similar materials  
 No toxicity at the limit of solubility.

**Ezetimibe / Atorvastatin Formulation**

Version 4.3      Revision Date: 09/13/2019      SDS Number: 26495-00013      Date of last issue: 24.04.2019  
Date of first issue: 29.10.2014

---

- Toxicity to algae/aquatic plants : EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility.
- NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials
- Toxicity to microorganisms : EC10 (Pseudomonas putida): > 100 mg/l  
Exposure time: 16 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

**Persistence and degradability****Components:****Cellulose:**

Biodegradability : Result: Readily biodegradable.

**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

**Magnesium stearate:**

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

**Bioaccumulative potential****Components:****Atorvastatin:**

Partition coefficient: n-octanol/water : log Pow: 1.62



**Ezetimibe / Atorvastatin Formulation**

Version 4.3      Revision Date: 09/13/2019      SDS Number: 26495-00013      Date of last issue: 24.04.2019  
Date of first issue: 29.10.2014

---

**Ezetimibe:**

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

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

**Magnesium stearate:**

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

**Mobility in soil****Components:****Atorvastatin:**

Distribution among environmental compartments : log Koc: 2.84

**Ezetimibe:**

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

**Other adverse effects**

No data available

---

**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.  
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

---

**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

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

**IATA-DGR**

UN/ID No. : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Ezetimibe, Atorvastatin)  
Class : 9  
Packing group : III

---

**Ezetimibe / Atorvastatin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
4.3	09/13/2019	26495-00013	Date of first issue: 29.10.2014

---

Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 956  
Packing instruction (passenger aircraft) : 956  
Environmentally hazardous : yes

**IMDG-Code**

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

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

Not applicable for product as supplied.

**Domestic regulation****NOM-002-SCT**

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

**Special precautions for user**

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

---

**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

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

AICS : not determined  
DSL : not determined  
IECSC : not determined

## Ezetimibe / Atorvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
4.3	09/13/2019	26495-00013	Date of first issue: 29.10.2014

## SECTION 16. OTHER INFORMATION

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
 NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average  
 NOM-010-STPS-2014 / VLE- : Time weighted average limit value  
 PPT

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 09/13/2019

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

# SAFETY DATA SHEET



## Ezetimibe / Atorvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
4.3	09/13/2019	26495-00013	Date of first issue: 29.10.2014

---

MX / Z8