SAFETY DATA SHEET

Ezetimibe / Atorvastatin Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ezetimibe / Atorvastatin Formulation

Manufacturer or supplier’s details
Company : Organon & Co.
Address : Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil B-2220
Telephone : 551-430-6000
Emergency telephone : 215-631-6999
E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Liver, muscle)
Long-term (chronic) aquatic hazard : Category 2

GHS label elements in accordance with ABNT NBR 14725 Standard
Hazard pictograms :

Signal Word : Warning
Hazard Statements : H373 May cause damage to organs (Liver, muscle) through prolonged or repeated exposure if swallowed. H411 Toxic to aquatic life with long lasting effects.
Precautionary Statements :
Prevention:
P260 Do not breathe dust.
P273 Avoid release to the environment.
Response:
P314 Get medical advice/ attention if you feel unwell.
P391 Collect spillage.
SAFETY DATA SHEET

Ezetimibe / Atorvastatin Formulation

Other hazards which do not result in classification
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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 20 - &lt; 30</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Atorvastatin</td>
<td>134523-03-8</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ezetimibe</td>
<td>163222-33-1</td>
<td>&gt;= 2,5 - &lt; 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting:
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 (NOx)
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 so.
Evacuate area.

Special protective equipment for fire-fighters:
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 (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

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.
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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Atorvastatin</td>
<td>134523-03-8</td>
<td>TWA</td>
<td>0.05 mg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.5 mg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Ezetimibe</td>
<td>163222-33-1</td>
<td>TWA</td>
<td>25 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>250 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
Engineering measures: All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

Personal protective equipment
- **Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Filter type: Particulates type
- **Hand protection**: Material: Chemical-resistant gloves
- **Remarks**: Consider double gloving.
- **Eye protection**: Material: Chemical-resistant glasses. 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**: Material: 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.
## SECTION 10. STABILITY AND REACTIVITY

| Property                                      | Category                                      | Description                                                                 |
|-----------------------------------------------|-----------------------------------------------|                                                                            |
| 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)                               | 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 11. TOXICOLOGICAL INFORMATION
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
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

**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
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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.

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

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)
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
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Ezetimibe / Atorvastatin Formulation

<table>
<thead>
<tr>
<th>Application Route: Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developmental Toxicity: NOAEL: 100 mg/kg body weight</td>
</tr>
<tr>
<td>Result: No embryo-fetal toxicity.</td>
</tr>
</tbody>
</table>

**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  
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: \( \geq 9.000 \text{ mg/kg} \)  
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  
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: \( > 100 \text{ mg/kg} \)  
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:
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
### 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.

#### 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.

#### 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.

#### M-Factor (Chronic aquatic toxicity)
- **M-Factor:** 1

#### 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  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility.

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

Bioaccumulation:
Components:

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

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
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

ANTT
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Ezetimibe, Atorvastatin)
Class : 9
Packing group : III
Labels : 9
Hazard Identification Number : 90

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.
SAFETY DATA SHEET

Ezetimibe / Atorvastatin Formulation

Version 4.1
Revision Date: 16.10.2020
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Date of first issue: 29.10.2014

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Sodium hydrogencarbonate

International Regulations

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

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

SECTION 16. OTHER INFORMATION

Further information


Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average

All additional information and abbreviations are listed here.

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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.