SECTION 1. IDENTIFICATION

Product name : Ezetimibe / Atorvastatin Formulation
Other means of identification : No data available

Manufacturer or supplier's details
Company name of supplier : Organon & Co.
Address : 30 Hudson Street, 33nd floor
Jersey City, New Jersey, U.S.A 07302
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
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Liver, muscle)

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 attention if you feel unwell.
Disposal:
P501 Dispose of contents and 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

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>No data available</td>
<td>9004-34-6</td>
<td>&gt;= 10 - &lt; 30 *</td>
<td></td>
</tr>
<tr>
<td>Atorvastatin</td>
<td>No data available</td>
<td>134523-03-8</td>
<td>&gt;= 10 - &lt; 30 *</td>
<td></td>
</tr>
<tr>
<td>Ezetimibe</td>
<td>No data available</td>
<td>163222-33-1</td>
<td>&gt;= 1 - &lt; 5 *</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 5 *</td>
<td></td>
</tr>
</tbody>
</table>

* Actual concentration or concentration range is withheld as a trade secret

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 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 (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 and Advice on safe handling: Use only with adequate ventilation. 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.

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>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA EV (total dust)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></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</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></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: Chemical-resistant gloves

**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.

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.

### 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)
   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 reac-tions : 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
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
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

**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
SAFETY DATA SHEET

Ezetimibe / Atorvastatin Formulation

Version 3.7  Revision Date: 04/09/2021  SDS Number: 26475-00017  Date of last issue: 10/16/2020  Date of first issue: 10/29/2014

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
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.

**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
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:
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)):
Exposure time: 48 h
Remarks: Based on data from similar materials

Atorvastatin:
Toxicity to fish:
LC50 (Pimephales promelas (fathead minnow)):
Exposure time: 96 h
Method: OECD Test Guideline 203

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

Toxicity to algae/aquatic plants:
EC50 (Pseudokirchneriella subcapitata (green algae)):
Exposure time: 72 h
Method: OECD Test Guideline 201
<table>
<thead>
<tr>
<th>Property</th>
<th>NOEC/EC50 (Concentration)</th>
<th>Exposure Time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC (Pimephales promelas (fathead minnow)): 0.49 mg/l</td>
<td>33 d</td>
<td>OECD Test Guideline 210</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 4 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 0.317 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 201</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td></td>
<td>NOEC (Pimephales promelas (fathead minnow)): 0.051 mg/l</td>
<td>33 d</td>
<td>OECD Test Guideline 210</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Cyprinodon variegatus (sheepshead minnow)): 4 mg/l</td>
<td>7 d</td>
<td></td>
<td>No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td></td>
<td>NOEC (Daphnia magna (Water flea)): 0.282 mg/l</td>
<td>21 d</td>
<td></td>
<td>No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td></td>
<td>EC50: &gt; 4.4 mg/l</td>
<td>3 h</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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 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):

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

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 %
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:  
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

**TDG**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe, Atorvastatin)
- Class: 9
SAFETY DATA SHEET

Ezetimibe / Atorvastatin Formulation

Version 3.7 Revision Date: 04/09/2021 SDS Number: 26475-00017 Date of last issue: 10/16/2020
Date of first issue: 10/29/2014

Packing group : III
Labels : 9
ERG Code : 171
Marine pollutant : yes (Ezetimibe, Atorvastatin)

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

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL : Canada. British Columbia OEL
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA : 8-hour, time-weighted average
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average
CA QC OEL / TWAEV : Time-weighted average exposure value

AIIIC - Australian Inventory of Industrial Chemicals; 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; LDS0 - 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

Revision Date: 04/09/2021
Date format: mm/dd/yyyy

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.

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