SAFETY DATA SHEET

Ezetimibe / Atorvastatin Formulation

Version 7.3  Revision Date: 10/16/2020  SDS Number: 26504-00015  Date of last issue: 03/23/2020  Date of first issue: 10/29/2014

SECTION 1. IDENTIFICATION

Product name: Ezetimibe / Atorvastatin Formulation

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Combustible dust

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

GHS label elements
Hazard pictograms:  
Signal Word: Warning
Hazard Statements: If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air. 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.
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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

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

Actual concentration 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)

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 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>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</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**
  - General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any
hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material : 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.
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 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
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
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- **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
- **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
- **Genotoxicity in vitro**: Test Type: reverse mutation assay Test system: Escherichia coli Result: negative
- **Genotoxicity in vitro**: Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster lung cells Result: negative
- **Genotoxicity in vitro**: 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

IARC: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP: No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**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  
Species: Rat, male and female 
Fertility: NOAEL: > 1,000 mg/kg body weight 
Result: No effects on fertility, No fetotoxicity.

Effects on fetal 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  
Species: Rat 
Application Route: Ingestion 
Method: OECD Test Guideline 422 
Result: negative 
Remarks: Based on data from similar materials

Effects on 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:

- **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.

### Experience with human exposure

#### Components:

**Ezetimibe:**

- Not applicable

**Atorvastatin:**

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

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### 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
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<tr>
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#### 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

**Exposure time: 72 h**
**Method: OECD Test Guideline 201**

**Remarks:** No toxicity at the limit of solubility.

**Toxicity to fish (Chronic toxicity):**

- **NOEC** (Pimephales promelas (fathead minnow)): 0.49 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

**Remarks:** No toxicity at the limit of solubility.

**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.

- **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
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

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

49 CFR

<table>
<thead>
<tr>
<th>UN/ID/NA number</th>
<th>Proper shipping name</th>
<th>Class</th>
<th>Packing group</th>
<th>Labels</th>
<th>ERG Code</th>
<th>Marine pollutant</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN 3077</td>
<td>Environmentally hazardous substance, solid, n.o.s. (Ezetimibe, Atorvastatin)</td>
<td>9</td>
<td>III</td>
<td>CLASS 9</td>
<td>171</td>
<td>yes (Ezetimibe, Atorvastatin)</td>
<td>Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.</td>
</tr>
</tbody>
</table>

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

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards

<table>
<thead>
<tr>
<th>Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combustible dust</td>
</tr>
<tr>
<td>Specific target organ toxicity (single or repeated exposure)</td>
</tr>
</tbody>
</table>

SARA 313

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.</td>
<td></td>
</tr>
</tbody>
</table>

US State Regulations

Pennsylvania Right To Know

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>D-Glucose, 4-O-.beta.-D-galactopyranosyl-, monohydrate</td>
<td>64044-51-5</td>
</tr>
<tr>
<td>Lactose</td>
<td>63-42-3</td>
</tr>
<tr>
<td>Atorvastatin</td>
<td>134523-03-8</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
</tr>
</tbody>
</table>

California List of Hazardous Substances

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyvinyl pyrrolidone</td>
<td>9003-39-8</td>
</tr>
</tbody>
</table>

California Permissible Exposure Limits for Chemical Contaminants

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
</tbody>
</table>
Magnesium stearate 557-04-0

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

NFPA 704:

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Instability</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® IV:

- HEALTH: * 2
- FLAMMABILITY: 3
- PHYSICAL HAZARD: 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- NIOSH REL: USA. NIOSH Recommended Exposure Limits
- OSHA Z-1: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- ACGIH / TWA: 8-hour, time-weighted average
- NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
- OSHA Z-1 / TWA: 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC
SAFETY DATA SHEET

Ezetimibe / Atorvastatin Formulation

Version 7.3  Revision Date: 10/16/2020  SDS Number: 26504-00015  Date of last issue: 03/23/2020  Date of first issue: 10/29/2014

- 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative


Revision Date: 10/16/2020

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.

US / Z8