1.1 Product identifier

Trade name: Ezetimibe / Atorvastatin Formulation

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

Use of the Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet

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

Telephone: 44 1 670 59 30 00
Telefax: 908-735-1496

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

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Specific target organ toxicity - repeated exposure, Category 2: H373: May cause damage to organs through prolonged or repeated exposure.

Long-term (chronic) aquatic hazard, Category 2: H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms: 

Signal word: Warning

Hazard statements: 

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

Precautionary statements: Prevention:
Ezetimibe / Atorvastatin Formulation

2.3 Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
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<tbody>
<tr>
<td>Atorvastatin</td>
<td>134523-03-8</td>
<td>STOT RE2; H373</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aquatic Chronic2; H411</td>
<td></td>
</tr>
<tr>
<td>Ezetimibe</td>
<td>163222-33-1</td>
<td>Aquatic Chronic1; H410</td>
<td>&gt;= 2.5 - &lt; 10</td>
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<tr>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 1</td>
<td></td>
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</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice: In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled: If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact: Wash with water and soap.
Get medical attention if symptoms occur.
In case of eye contact: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed
Risks: May cause damage to organs through prolonged or repeated exposure.
Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
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

5.3 Advice for firefighters
Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Do not breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures:
If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers: Keep in properly labelled containers. Store in accordance with the particular national regulations.
Advice on common storage: Do not store with the following product types: Strong oxidizing agents

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
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<tbody>
<tr>
<td>Atorvastatin</td>
<td>134523-03-8</td>
<td>TWA</td>
<td>0.05 mg/m³ (OEB 3)</td>
<td>Internal</td>
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<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.5 mg/100 cm²</td>
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<td>TWA</td>
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<td></td>
<td></td>
<td>Wipe limit</td>
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</table>

8.2 Exposure controls

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

Personal protective equipment
Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

Skin and body protection:

Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Respiratory protection:

If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

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<thead>
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<th>Property</th>
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<td>Appearance</td>
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<td>Initial boiling point and boiling range</td>
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<td>Flash point</td>
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<tr>
<td>Evaporation rate</td>
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<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
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<td>Upper explosion limit / Upper flammability limit</td>
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<tr>
<td>Lower explosion limit / Lower flammability limit</td>
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<td>Vapour pressure</td>
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<tr>
<td>Relative vapour density</td>
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</tr>
</tbody>
</table>
Ezetimibe / Atorvastatin Formulation

Relative density : No data available
Density : No data available
Solubility(ies) : 
Water solubility : 0.01 g/l
Partition coefficient: n-octanol/water : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity : 
Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information
Flammability (liquids) : No data available
Molecular weight : No data available
Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

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

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

10.5 Incompatible materials
Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.
SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

Components:

Atorvastatin:
- Acute oral toxicity:
  - LD50 (Rat, male and female): > 5.000 mg/kg
  - LD50 (Mouse, male and female): > 5.000 mg/kg
- LD50 (Dog): > 3.000 mg/kg

Ezetimibe:
- Acute oral toxicity:
  - LD50 (Rat): > 5.000 mg/kg
  - LD50 (Mouse): > 5.000 mg/kg
  - LD50 (Dog): > 3.000 mg/kg
- Acute inhalation toxicity:
  - Remarks: No data available
- Acute dermal toxicity:
  - Remarks: No data available
- Acute toxicity (other routes of administration):
  - LD50 (Rat): > 2.000 mg/kg
    Application Route: Intraperitoneal
  - LD50 (Mouse): > 1.000 - < 2.000 mg/kg
    Application Route: Intraperitoneal

Skin corrosion/irritation
Not classified based on available information.

Components:

Atorvastatin:
- Species: Rabbit
- Result: No skin irritation

Ezetimibe:
- Species: Rabbit
- Result: No skin irritation

Serious eye damage/eye irritation
Not classified based on available information.
Components:

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

Ezetimibe:
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

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

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

Germ cell mutagenicity
Not classified based on available information.

Components:

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

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

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

Test Type: sister chromatid exchange assay
Test system: Chinese hamster lung cells
# Ezetimibe / Atorvastatin Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
</table>

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

### Ezetimibe: Genotoxicity in vivo
- **Test Type:** Micronucleus test
  - **Species:** Mouse
  - **Cell type:** Bone marrow
  - **Application Route:** Oral
  - **Result:** negative

### Carcinogenicity
Not classified based on available information.

### Components:

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

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

#### Ezetimibe:
- **Species:** Rat, female
- **Application Route:** oral (feed)
- **Exposure time:** 104 weeks
- **Result:** negative

- **Species:** Rat, male
- **Application Route:** oral (feed)
- **Exposure time:** 104 weeks
Result: negative

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

Reproductive toxicity
Not classified based on available information.

Components:

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

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

Ezetimibe:
Effects on fertility:
- Test Type: Fertility/early embryonic development
  Species: Rat, male and female
  Fertility: NOAEL: > 1.000 mg/kg body weight
  Result: No effects on fertility, No fetotoxicity

Effects on foetal development:
- Test Type: Development
  Species: Rat
  Application Route: Oral
  Developmental Toxicity: NOAEL: > 1.000 mg/kg body weight
  Result: No adverse effects
- Test Type: Development
  Species: Rabbit
  Application Route: Oral
  Developmental Toxicity: NOAEL: > 1.000 mg/kg body weight
  Result: No adverse effects
Ezetimibe / Atorvastatin Formulation

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.

Components:

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

Repeated dose toxicity

Components:

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

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

Ezetimibe:
- Species: Dog
- NOAEL: 1.000 mg/kg
- Application Route: Oral
- Exposure time: 90 d
- Remarks: No significant adverse effects were reported

Species: Rat
- NOAEL: 1.500 mg/kg
- Application Route: Oral
- Exposure time: 90 d
- Remarks: No significant adverse effects were reported

Species: Mouse
- NOAEL: 500 mg/kg
- Application Route: Oral
- Exposure time: 90 d
- Remarks: No significant adverse effects were reported

Species: Dog
- NOAEL: 300 mg/kg
- Application Route: Oral
Exposure time: 1 yr
Remarks: No significant adverse effects were reported

**Aspiration toxicity**
Not classified based on available information.

**Components:**

**Ezetimibe:**
Not applicable

**Experience with human exposure**

**Components:**

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

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

### SECTION 12: Ecological information

#### 12.1 Toxicity

**Components:**

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

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

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

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

Toxicity to microorganisms: EC50: > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Toxicity to fish (Chronic toxicity):
- NOEC: 0.49 mg/l
  - Exposure time: 33 d
  - Species: *Pimephales promelas* (fathead minnow)
  - Method: OECD Test Guideline 210

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

**Ezetimibe:**

Toxicity to fish:
- LC50 (*Pimephales promelas* (fathead minnow)): > 0.125 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
  - Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (*Daphnia magna* (Water flea)): > 4 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
  - Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants:
- EC50 (*Pseudokirchneriella subcapitata* (green algae)): > 0.317 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 201
  - Remarks: No toxicity at the limit of solubility

  NOEC (*Pseudokirchneriella subcapitata* (green algae)): 0.317 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 201
  - Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms:
- EC50: > 4.4 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209
  - Remarks: No toxicity at the limit of solubility

  NOEC: 4.4 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209
  - Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity):
- NOEC: 0.051 mg/l
  - Exposure time: 33 d
  - Species: *Pimephales promelas* (fathead minnow)
  - Method: OECD Test Guideline 210

  NOEC: 4 mg/l
  - Exposure time: 7 d
  - Species: *Cyprinodon variegatus* (sheepshead minnow)
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

- NOEC: 0.282 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)
- Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic toxicity) : 1

12.2 Persistence and degradability

**Components:**

**Atorvastatin:**
- Biodegradation: Result: Not readily biodegradable.
- Biodegradation: 7.7 %
- Exposure time: 28 d
- Method: OECD Test Guideline 314

**Ezetimibe:**
- Biodegradation: Result: Not readily biodegradable.
- Biodegradation: 6.8 %
- Exposure time: 28 d

**Stability in water:**
- Hydrolysis: 50 % (4.5 d)
- Method: OECD Test Guideline 111

12.3 Bioaccumulative potential

**Components:**

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

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

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

12.4 Mobility in soil

**Components:**

**Atorvastatin:**
- Distribution among environmental compartments: log Koc: 2.84

**Ezetimibe:**
- Distribution among environmental compartments: log Koc: 4.35
mental compartments

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

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

SECTION 14: Transport information

14.1 UN number
ADN: UN 3077
ADR: UN 3077
RID: UN 3077
IMDG: UN 3077
IATA: UN 3077

14.2 UN proper shipping name
ADN: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe, Atorvastatin)
ADR: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe, Atorvastatin)
RID: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe, Atorvastatin)
IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe, Atorvastatin)
IATA: Environmentally hazardous substance, solid, n.o.s. (Ezetimibe, Atorvastatin)

14.3 Transport hazard class(es)
ADN: 9
Ezetimibe / Atorvastatin Formulation

14.4 Packing group

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<td>III</td>
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<table>
<thead>
<tr>
<th>Packing group</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
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<tr>
<td>Packing instruction (passenger aircraft)</td>
<td>956</td>
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<tr>
<td>Packing instruction (LQ)</td>
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<tr>
<td>Labels</td>
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14.5 Environmental hazards

<table>
<thead>
<tr>
<th>Packing group</th>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
</tr>
</thead>
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<tr>
<td>Environmentally hazardous</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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Marine pollutant : yes
IATA (Passenger) Environmentally hazardous : yes
IATA (Cargo) Environmentally hazardous : yes

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

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mix-
ture
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances,
preparations and articles (Annex XVII) : Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that de-
plete the ozone layer : Not applicable
Regulation (EC) No 850/2004 on persistent organic pol-
lutants : Not applicable
Regulation (EC) No 649/2012 of the European Parlia-
ment and the Council concerning the export and import
of dangerous chemicals : Not applicable
major-accident hazards involving dangerous substances.

<table>
<thead>
<tr>
<th>E2</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>200 t</td>
<td>500 t</td>
</tr>
</tbody>
</table>

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

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined
SAFETY DATA SHEET
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**Ezetimibe / Atorvastatin Formulation**

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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

**SECTION 16: Other information**

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

**Full text of H-statements**

- **H373**: May cause damage to organs through prolonged or repeated exposure if swallowed.
- **H410**: Very toxic to aquatic life with long lasting effects.
- **H411**: Toxic to aquatic life with long lasting effects.

**Full text of other abbreviations**

- Aquatic Chronic: Long-term (chronic) aquatic hazard
- STOT RE: Specific target organ toxicity - repeated exposure
- ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS: Australian Inventory of Chemical Substances; ASTM: American Society for the Testing of Materials; bw: Body weight; CLP: Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR: Carcinogen, Mutagen or Reproductive Toxicant; DIN: Standard of the German Institute for Standardisation; DSL: Domestic Substances List (Canada); ECHA: European Chemicals Agency; EC-Number: European Community number; ECx: Concentration associated with x% response; ELx: Loading rate associated with x% response; EmS: Emergency Schedule; ENCS: Existing and New Chemical Substances (Japan); ErCx: Concentration associated with x% growth rate response; GHS: Globally Harmonized System; GLP: Good Laboratory Practice; IARC: International Agency for Research on Cancer; IATA: International Air Transport Association; IBC: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50: Half maximal inhibitory concentration; ICAO: International Civil Aviation Organization; IECSC: Inventory of Existing Chemical Substances in China; IMDG: International Maritime Dangerous Goods; IMO: International Maritime Organization; ISHL: Industrial Safety and Health Law (Japan); ISO: International Organisation for Standardization; KECI: Korea Existing Chemicals Inventory; LC50: Lethal Concentration to 50 % of a test population; LD50: Lethal Dose to 50% of a test population; MARPOL: International Convention for the Prevention of Pollution from Ships; n.o.s.: Not Otherwise Specified; NO(A)EC: No Observed (Adverse) Effect Concentration; NO(A)EL: No Observed (Adverse) Effect Level; NOELR: No Observable Effect Loading Rate; NZIoC: New Zealand Inventory of Chemicals; OECD: Organization for Economic Co-operation and Development; OPPTS: Office of Chemical Safety and Pollution Prevention; PBT: Persistent, Bioaccumulative and Toxic substance; PICCS: Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR: (Quantitative) Structure Activity Relationship; REACH: Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID: Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT: Self-Accelerating Decomposition Temperature; SDS: Safety Data Sheet; SVHC: Substance of very high concern; TCSI: Taiwan Chemical Substance Inventory; TSCA: Toxic Substances Control Act (United States); UN: United Nations; UNRTDG: United Nations Recommendations on the Transport of Dangerous Goods; vPvB: Very Persistent and Very Bioaccumulative

Further information
## Ezetimibe / Atorvastatin Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
</table>

**Sources of key data used to compile the Safety Data Sheet:**


**Classification of the mixture:**

<table>
<thead>
<tr>
<th>STOT RE 2</th>
<th>H373</th>
<th>Calculation method</th>
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</thead>
<tbody>
<tr>
<td>Aquatic Chronic 2</td>
<td>H411</td>
<td>Calculation method</td>
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</table>

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

NO / EN