SECTION 1: Identification of the substance/mixture and of the company/undertaking

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
   Long-term (chronic) aquatic hazard, Category 2
   H373: May cause damage to organs through prolonged or repeated exposure.
   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:
P260  Do not breathe dust.
P273  Avoid release to the environment.

Response:
P314  Get medical advice/ attention if you feel unwell.
P391  Collect spillage.

Hazardous components which must be listed on the label:
Atorvastatin

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>EC-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>EC-No.</td>
<td>Index-No.</td>
<td>Registration number</td>
<td></td>
</tr>
<tr>
<td>Atorvastatin</td>
<td>134523-03-8</td>
<td></td>
<td>STOT RE 2; H373 Aquatic Chronic 2; H411</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Ezetimibe</td>
<td>163222-33-1</td>
<td></td>
<td>Aquatic Chronic 1; H410</td>
<td>&gt;= 2.5 - &lt; 10</td>
</tr>
</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.
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according to Regulation (EC) No. 1907/2006

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Date of first issue: 29.10.2014

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.
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

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 as-
5 / 20

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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>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA (inhalable dust)</td>
<td>10 mg/m³</td>
<td>GB EH40</td>
</tr>
</tbody>
</table>

Further information

For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols. The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg/m³ 8-hour TWA of inhalable dust or 4 mg/m³ 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits. Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed ‘inhalable’ and ‘respirable’. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breath-
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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

- **Appearance**: powder
- **Colour**: off-white
- **Odour**: No data available
- **Odour 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.
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapour pressure**: No data available
- **Relative vapour 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
  - **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
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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

Ezetimibe:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
                   LD50 (Mouse): > 5,000 mg/kg
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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
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according to Regulation (EC) No. 1907/2006

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<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>

### 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  
    Result: negative

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

#### Ezetimibe:
- **Genotoxicity in vitro**
  - Test Type: Bacterial reverse mutation assay (AMES)  
    Metabolic activation: with and without metabolic activation  
    Result: negative
  - Test Type: Chromosomal aberration  
    Test system: Human lymphocytes  
    Result: negative

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

### Ezetimibe:

- **Test Type**: Maximisation Test
  - Species: Guinea pig  
  - 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 develop-: Species: Rat, female
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Developmental Toxicity: NOAEL: 20 mg/kg body weight
Result: No teratogenic effects, Embryo-foetal toxicity
Remarks: Maternal toxicity observed.
Species: Rabbit, female
Application Route: Oral
Developmental Toxicity: NOAEL: 100 mg/kg body weight
Result: No embryo-foetal 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 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

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 route: 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
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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:**

**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

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  
Method: OECD Test Guideline 106

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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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Version: 2.3
Revision Date: 09/13/2019
SDS Number: 26486-00013
Date of last issue: 24.04.2019
Date of first issue: 29.10.2014

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

ADN : 9
ADR : 9
RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

ADN
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

ADR
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID
Packing group : III
Classification Code : M7
Hazard Identification Number : 90

Environmentally hazardous substance, solid, n.o.s.
(Ezetimibe, Atorvastatin)
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Labels : 9

IMDG
Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)
Packing instruction (cargo aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
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 variations 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 mixture

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
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Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants: Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable

Quantity 1 Quantity 2
E2 ENVIRONMENTAL HAZARDS 200 t 500 t

Other regulations:
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

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
GB EH40: UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA: Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL: Short-term exposure limit (15-minute reference period)
**SAFETY DATA SHEET**

according to Regulation (EC) No. 1907/2006

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**Ezetimibe / Atorvastatin Formulation**

**Version**: 2.3  
**Revision Date**: 09/13/2019  
**SDS Number**: 26486-00013  
**Date of last issue**: 24.04.2019  
**Date of first issue**: 29.10.2014

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**Further information**


**Classification of the mixture:**  
**Classification procedure:**

<table>
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<tr>
<th>Stabiliser</th>
<th>Classification</th>
<th>moon%h373</th>
<th>Calculation method</th>
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<td>STOT RE 2</td>
<td>H373</td>
<td>Calculation method</td>
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<tr>
<td>Aquatic Chronic 2</td>
<td>H411</td>
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GB / EN