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

Ezetimibe Formulation

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

1.1 Product identifier
   Trade name : Ezetimibe 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)
   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 :

   Hazard statements : H411 Toxic to aquatic life with long lasting effects.
   Precautionary statements :
   Prevention: P273 Avoid release to the environment.
   Response: P391 Collect spillage.
2.3 Other hazards

Dust contact with the eyes can lead to mechanical irritation.
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>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ezetimibe</td>
<td>163222-33-1</td>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic1; H410</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 1</td>
<td></td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
<td>205-788-1</td>
<td></td>
<td></td>
<td>Acute Tox.4; H302 Skin Irrit.2; H315 Eye Dam.1; H318 Aquatic Chronic3; H412</td>
<td>&gt;= 1 - &lt; 2,5</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 : In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

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: 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
- Sulphur oxides
- 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 so.
- Evacuate area.

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 get on skin or clothing.
Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
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

Occupational Exposure Limits

<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>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>
</tbody>
</table>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>285 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>4060 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>85 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>2440 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>24 mg/kg bw/day</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>Fresh water</td>
<td>0.176 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.018 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1.35 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>6.97 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.697 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>1.29 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>
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: No data available
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.

Product:
- Acute oral toxicity: Acute toxicity estimate: > 2.000 mg/kg
  Method: Calculation method

Components:
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

Sodium n-dodecyl sulfate:
- Acute oral toxicity: LD50 (Rat): 1.200 mg/kg
  Method: OECD Test Guideline 401
- Acute dermal toxicity: LD50 (Rat): > 2.000 mg/kg
  Method: OECD Test Guideline 402
  Remarks: Based on data from similar materials
Skin corrosion/irritation
Not classified based on available information.

Components:

Ezetimibe:
Species : Rabbit
Result : No skin irritation

Sodium n-dodecyl sulfate:
Species : Rabbit
Result : Skin irritation

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

Components:

Ezetimibe:
Species : Rabbit
Result : No eye irritation

Sodium n-dodecyl sulfate:
Species : Rabbit
Method : OECD Test Guideline 405
Result : Irreversible effects on the eye

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

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

Sodium n-dodecyl sulfate:
Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative
Remarks : Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.
Components:

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

Sodium n-dodecyl sulfate:
- Genotoxicity in vitro:
  - Test Type: Bacterial reverse mutation assay (AMES)
    Method: OECD Test Guideline 471
    Result: negative

  - Test Type: In vitro mammalian cell gene mutation test
    Result: negative

- Genotoxicity in vivo:
  - Test Type: Rodent dominant lethal test (germ cell) (in vivo)
    Species: Mouse
    Application Route: Ingestion
    Result: negative

Carcinogenicity
Not classified based on available information.

Components:

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
Sodium n-dodecyl sulfate:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Method: OECD Test Guideline 453
Result: negative
Remarks: Based on data from similar materials

Reproductive toxicity
Not classified based on available information.

Components:

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:
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: > 1.000 mg/kg body weight
Result: No adverse effects

Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: > 1.000 mg/kg body weight
Result: No adverse effects

Sodium n-dodecyl sulfate:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative
Remarks: Based on data from similar materials

Effects on foetal 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
Not classified based on available information.
Repeated dose toxicity

Components:

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

Sodium n-dodecyl sulfate:
Species : Rat
NOAEL : 488 mg/kg
Application Route : Ingestion
Exposure time : 90 Days
Remarks : Based on data from similar materials

Aspiration toxicity
Not classified based on available information.

Components:

Ezetimibe:
Not applicable

Experience with human exposure

Components:

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:**

**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
ic toxicity)  
Species: Daphnia magna (Water flea)  
Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic toxicity):  
: 1

**Sodium n-dodecyl sulfate:**

Toxicity to fish:  
LC50 (Pimephales promelas (fathead minnow)): 29 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:  
EC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants:  
ErC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l  
Exposure time: 72 h  
NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l  
Exposure time: 72 h

Toxicity to microorganisms:  
EC50: 135 mg/l  
Exposure time: 3 h

Toxicity to fish (Chronic toxicity):  
NOEC: >= 1,357 mg/l  
Exposure time: 42 d  
Species: Pimephales promelas (fathead minnow)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):  
NOEC: 0.88 mg/l  
Exposure time: 7 d  
Species: Ceriodaphnia dubia (water flea)

### 12.2 Persistence and degradability

**Components:**

**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

**Sodium n-dodecyl sulfate:**

Biodegradability:  
Result: Readily biodegradable.  
Biodegradation: 95 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

### 12.3 Bioaccumulative potential

**Components:**

**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

Sodium n-dodecyl sulfate:  
Partition coefficient: n-octanol/water: log Pow: 0.83

12.4 Mobility in soil

Components:

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

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 Formulation

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe)

IATA : Environmentally hazardous substance, solid, n.o.s. (Ezetimibe)

14.3 Transport hazard class(es)

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

14.4 Packing group

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

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

IMDG
Packing group : III
Labels : 9

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

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 - 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 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

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
H302 : Harmful if swallowed.
H315 : Causes skin irritation.
H318 : Causes serious eye damage.
H410 : Very toxic to aquatic life with long lasting effects.
H412 : Harmful to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Dam. : Serious eye damage
Skin Irrit. : Skin irritation

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 (Median Lethal Dose); 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
Ezetimibe Formulation

Further information


Classification of the mixture:  Classification procedure:

Aquatic Chronic 2  H411  Calculation method

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