SECTION 1. IDENTIFICATION

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

Manufacturer or supplier’s details
Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
          Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

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

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Ezetimibe</td>
<td>163222-33-1</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration or concentration range is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

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

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

In case of skin contact : 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.

Most important symptoms and effects, both acute and delayed: Dust contact with the eyes can lead to mechanical irritation.

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

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)
Fluorine compounds
Sulfur oxides
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 and personal protective equipment recommendations.

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.

Methods and materials for: Sweep up or vacuum up spillage and collect in suitable
containment and cleaning up 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: 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.

Conditions for safe storage: Keep in properly labeled containers. Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types: Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (total dust)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
</tbody>
</table>
Engineering measures: Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m³ - total dust, 5 mg/m³ - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m³ - respirable particles, 10 mg/m³ - inhalable particles.

Personal protective equipment

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

Filter type: Particulates type

Hand protection Material: Chemical-resistant gloves

Remarks: Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection: Wear the following personal protective equipment:
Safety goggles

Skin and body protection: Skin should be washed after contact.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: granular

Color: white

Odor: No data available
Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : Not applicable

Evaporation rate : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water
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.

Product:
  Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
      Method: Calculation method

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

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
Result : Irreversible effects on the eye
Method : OECD Test Guideline 405

Respiratory or skin sensitization
Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

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

Sodium n-dodecyl sulfate:
Test Type : Maximization Test
SAFETY DATA SHEET

Ezetimibe Granules Formulation

Version 2.3  Revision Date: 09/13/2019  SDS Number: 1563959-00006  Date of last issue: 04/24/2019  Date of first issue: 04/18/2017

Routes of exposure: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

Components:

Cellulose:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Test Type: In vitro mammalian cell gene mutation test Result: negative
Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

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:

Cellulose:
Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

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:

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

Ezetimibe:
Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat, male and female
Fertility: NOAEL: > 1,000 mg/kg body weight
Result: No effects on fertility., No fetotoxicity.

Effects on fetal development:
Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: > 1,000 mg/kg body weight
Result: No adverse effects.

Test Type: Development
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 fetal development:
Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Cellulose:
Species: Rat
NOAEL: >= 9,000 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

Ezetimibe:
Species: Dog
NOAEL: 1,000 mg/kg
Application Route: Oral
Exposure time: 90 d
Remarks: No significant adverse effects were reported
Species: Rat
SAFETY DATA SHEET

Ezetimibe Granules Formulation

Version 2.3  Revision Date: 09/13/2019  SDS Number: 1563959-00006  Date of last issue: 04/24/2019
Date of first issue: 04/18/2017

NOAEL: 1,500 mg/kg
Application Route: Oral
Exposure time: 90 d
Remarks: No significant adverse effects were reported

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

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

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, Diarrhea, flatulence, muscle pain, upper respiratory tract infection, Back pain, joint pain

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity
Components:
Cellulose:
Toxicity to fish: LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Ezetimibe:
### Toxicity to fish

<table>
<thead>
<tr>
<th>LC50 (Pimephales promelas (fathead minnow)):</th>
<th>&gt; 0.125 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 96 h</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 203</td>
<td></td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility.</td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>EC50 (Daphnia magna (Water flea)):</th>
<th>&gt; 4 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 48 h</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 202</td>
<td></td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility.</td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)):</th>
<th>&gt; 0.317 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 96 h</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NOEC (Pseudokirchneriella subcapitata (green algae)):</th>
<th>0.317 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 96 h</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility.</td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to fish (Chronic toxicity)

<table>
<thead>
<tr>
<th>NOEC (Pimephales promelas (fathead minnow)):</th>
<th>0.051 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 33 d</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 210</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NOEC (Cyprinodon variegatus (sheepshead minnow)):</th>
<th>4 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 7 d</td>
<td></td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility.</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>NOEC (Daphnia magna (Water flea)):</th>
<th>0.282 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 21 d</td>
<td></td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility.</td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>EC50:</th>
<th>&gt; 4.4 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 3 h</td>
<td></td>
</tr>
<tr>
<td>Test Type: Respiration inhibition</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 209</td>
<td></td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NOEC:</th>
<th>4.4 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 3 h</td>
<td></td>
</tr>
<tr>
<td>Test Type: Respiration inhibition</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 209</td>
<td></td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility.</td>
<td></td>
</tr>
</tbody>
</table>

### Sodium n-dodecyl sulfate:

#### Toxicity to fish

<table>
<thead>
<tr>
<th>LC50 (Pimephales promelas (fathead minnow)):</th>
<th>29 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 96 h</td>
<td></td>
</tr>
</tbody>
</table>

#### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>EC50 (Ceriodaphnia dubia (water flea)):</th>
<th>5.55 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 48 h</td>
<td></td>
</tr>
</tbody>
</table>

#### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>ErC50 (Desmodesmus subspicatus (green algae)):</th>
<th>&gt; 120 mg/l</th>
</tr>
</thead>
</table>
plants

Exposure time: 72 h

NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l
Exposure time: 72 h

Toxicity to fish (Chronic toxicity):

NOEC (Pimephales promelas (fathead minnow)): \( \geq 1.357 \) mg/l
Exposure time: 42 d

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

NOEC (Ceriodaphnia dubia (water flea)): 0.88 mg/l
Exposure time: 7 d

Toxicity to microorganisms:

EC50: 135 mg/l
Exposure time: 3 h

Persistence and degradability

Components:

Cellulose:

Biodegradability:
Result: Readily biodegradable.

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

Bioaccumulative potential

Components:

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

Sodium n-dodecyl sulfate:

Partition coefficient: n-octanol/water:
log Pow: 0.83
Mobility in soil

Components:

**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)

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)

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)

Class : 9

Packing group : III

Labels : 9

EmS Code : F-A, S-F

Marine pollutant : yes
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

TDG
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe)
Class : 9
Packing group : III
Labels : 9
ERG Code : 171
Marine pollutant : yes (Ezetimibe)

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

SECTION 15. REGULATORY INFORMATION

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

SECTION 16. OTHER INFORMATION

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

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized Sys-
SAFETY DATA SHEET

Ezetimibe Granules Formulation

Version: 2.3
Revision Date: 09/13/2019
SDS Number: 1563959-00006
Date of last issue: 04/24/2019
Date of first issue: 04/18/2017

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