SAFETY DATA SHEET

Ezetimibe Granules Formulation

SECTION 1. IDENTIFICATION

Product name: Ezetimibe Granules Formulation

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 29 CFR 1910.1200
Combustible dust

GHS label elements

Signal Word: Warning

Hazard Statements: If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.

Other hazards
Dust contact with the eyes can lead to mechanical irritation.

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;= 20 - &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 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
Methods and materials for containment and cleaning up:
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
- Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

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

Local/Total ventilation:
- 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>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
</tbody>
</table>
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**Ezetimibe Granules Formulation**

**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**

- General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**Hand protection**

- Material: Chemical-resistant gloves

**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 : No data available
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, kinematic : No data available
Explosive properties : Not explosive
## Oxidizing properties
The substance or mixture is not classified as oxidizing.

## Molecular weight
No data available

## Particle size
No data available

### SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Reactivity</th>
<th>Not classified as a reactivity hazard.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Conditions to avoid</th>
<th>Heat, flames and sparks.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avoid dust formation.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Incompatible materials</th>
<th>Oxidizing agents</th>
</tr>
</thead>
</table>

| Hazardous decomposition products | No hazardous decomposition products are known. |

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

<table>
<thead>
<tr>
<th>Route</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td></td>
</tr>
<tr>
<td>Skin contact</td>
<td></td>
</tr>
<tr>
<td>Ingestion</td>
<td></td>
</tr>
<tr>
<td>Eye contact</td>
<td></td>
</tr>
</tbody>
</table>

#### Acute toxicity
Not classified based on available information.

**Product:**

<table>
<thead>
<tr>
<th>Route</th>
<th>Toxicity Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>&gt; 5,000 mg/kg</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>&gt; 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mist</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>&gt; 2,000 mg/kg</td>
</tr>
</tbody>
</table>

#### Components:

**Cellulose:**

<table>
<thead>
<tr>
<th>Route</th>
<th>Toxicity Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
</tr>
</tbody>
</table>

**Ezetimibe:**

<table>
<thead>
<tr>
<th>Route</th>
<th>Toxicity Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): &gt; 5,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50 (Dog): &gt; 3,000 mg/kg</td>
</tr>
</tbody>
</table>
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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
- 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

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

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

**NTP**  
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
**Reproductive toxicity**  
Not classified based on available information.

**Components:**

**Cellulose:**

<table>
<thead>
<tr>
<th>Effect</th>
<th>Test Type</th>
<th>Species</th>
<th>Route</th>
<th>Result</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>One-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Effects on fetal development</td>
<td>Fertility/early embryonic development</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
<td></td>
</tr>
</tbody>
</table>

**Ezetimibe:**

<table>
<thead>
<tr>
<th>Effect</th>
<th>Test Type</th>
<th>Species</th>
<th>Route</th>
<th>Result</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>Fertility/early embryonic development</td>
<td>Rat, male and female</td>
<td>Ingestion</td>
<td>No effects on fertility</td>
<td>No fetotoxicity.</td>
</tr>
<tr>
<td>Effects on fetal development</td>
<td>Development</td>
<td>Rat</td>
<td>Oral</td>
<td>NOAEL: &gt; 1,000 mg/kg body weight</td>
<td>No adverse effects.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rabbit</td>
<td>Oral</td>
<td>NOAEL: &gt; 1,000 mg/kg body weight</td>
<td>No adverse effects.</td>
</tr>
</tbody>
</table>

**Sodium n-dodecyl sulfate:**

<table>
<thead>
<tr>
<th>Effect</th>
<th>Test Type</th>
<th>Species</th>
<th>Route</th>
<th>Result</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>Two-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Effects on fetal development</td>
<td>Embryo-fetal development</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

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

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

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

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

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

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):** NOEC (Daphnia magna (Water flea)): 0.282 mg/l
Exposure time: 21 d
Remarks: No toxicity at the limit of solubility.
### Toxicity to microorganisms

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

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

### 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 fish (Chronic toxicity)

- **NOEC** (Pimephales promelas (fathead minnow)): >= 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

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

#### 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

Sodium n-dodecyl sulfate:

Partition coefficient: n-octanol/water

Mobility in soil

Components:

Ezetimibe:

Distribution among environmental compartments

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues
Contaminated packaging
Dispose of in accordance with local regulations.
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

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

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

EPCRA - Emergency Planning and Community Right-to-Know
CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.
SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Combustible dust

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
- D-Glucose, 4-O-.beta.-D-galactopyranosyl-, monohydrate 64044-51-5
- Cellulose 9004-34-6
- Polyvinyl pyrrolidone 9003-39-8
- Ezetimibe 163222-33-1
- Croscarmellose sodium 74811-65-7

California List of Hazardous Substances
- Polyvinyl pyrrolidone 9003-39-8

California Permissible Exposure Limits for Chemical Contaminants
- Cellulose 9004-34-6

The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Instability</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® IV:

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Physical Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

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

Full text of other abbreviations

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

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic sub-

Revision Date: 09/13/2019

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

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.