

**Ezetimibe Formulation**

Version 5.0      Revision Date: 09/13/2019      SDS Number: 23831-00013      Date of last issue: 2019/04/24  
Date of first issue: 2014/10/21

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**1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Ezetimibe Formulation

**Manufacturer or supplier's details**

Company : MSD  
Address : JL Raya Pandaan KM. 48  
Pandaan, Jawa Timur - Indonesia  
Telephone : 908-740-4000  
Emergency telephone number : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@msd.com  
Telefax : 908-735-1496

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical

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**2. HAZARDS IDENTIFICATION****GHS Classification**

Long-term (chronic) aquatic hazard : Category 2

**GHS label elements**

Hazard pictograms :



Signal word : None

Hazard statements : H411 Toxic to aquatic life with long lasting effects.

Precautionary statements :

**Prevention:**

P273 Avoid release to the environment.

**Response:**

P391 Collect spillage.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards which do not result in classification**

Dust contact with the eyes can lead to mechanical irritation.

May form explosive dust-air mixture during processing, handling or other means.

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**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 10 -< 30
Ezetimibe	163222-33-1	>= 10 -< 25
Sodium n-dodecyl sulfate	151-21-3	>= 1 -< 2.5
Magnesium stearate	557-04-0	< 10

**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.

**5. FIREFIGHTING MEASURES**

- Suitable extinguishing media : Water spray  
 Alcohol-resistant foam  
 Carbon dioxide (CO<sub>2</sub>)  
 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 (NO<sub>x</sub>)  
 Fluorine compounds

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Sulphur 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 firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
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### 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 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.
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### 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.

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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 labelled containers.  
 Store in accordance with the particular national regulations.

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

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
Ezetimibe	163222-33-1	TWA	25 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	250 µg/100 cm <sup>2</sup>	Internal
Magnesium stearate	557-04-0	NAB	10 mg/m <sup>3</sup>	ID OEL
	Further information: Adopted in Year 1996, Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals			
		TWA (Inhalable fraction)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable fraction)	3 mg/m <sup>3</sup>	ACGIH

**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

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 : Consider double gloving.

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

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Skin and body protection	: aerosols. 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.
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.

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**9. 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.
Flammability (liquids)	: No data available
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

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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.
Molecular weight	:	No data available
Particle size	:	No data available

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**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.

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**11. TOXICOLOGICAL INFORMATION**

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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**Acute toxicity**

Not classified based on available information.

**Product:**

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
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**Components:****Cellulose:**

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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

**Magnesium stearate:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
 Method: OECD Test Guideline 423  
 Assessment: The substance or mixture has no acute oral toxicity  
 Remarks: Based on data from similar materials  
 Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
 Remarks: Based on data from similar materials

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Ezetimibe:**

Species : Rabbit  
 Result : No skin irritation

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**Sodium n-dodecyl sulfate:**

Species : Rabbit  
Result : Skin irritation

**Magnesium stearate:**

Species : Rabbit  
Result : No skin irritation  
Remarks : Based on data from similar materials

**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

**Magnesium stearate:**

Species : Rabbit  
Result : No eye irritation  
Remarks : Based on data from similar materials

**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



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**Magnesium stearate:**

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406
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

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**Magnesium stearate:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
 Result: negative  
 Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro  
 Method: OECD Test Guideline 473  
 Result: negative  
 Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)  
 Result: negative  
 Remarks: Based on data from similar materials

**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.

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**Components:****Cellulose:**

Effects on fertility : Test Type: One-generation reproduction toxicity study  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

Effects on foetal 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 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

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

**Magnesium stearate:**

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
 Species: Rat  
 Application Route: Ingestion  
 Method: OECD Test Guideline 422  
 Result: negative  
 Remarks: Based on data from similar materials

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Effects on foetal development	:	Test Type: Embryo-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:****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 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

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**Magnesium stearate:**

Species : Rat  
 NOAEL : > 100 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

**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

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		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
M-Factor (Chronic aquatic toxicity)	:	1
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
Toxicity to microorganisms	:	EC50: 135 mg/l Exposure time: 3 h

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**Magnesium stearate:**

- Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l  
 Exposure time: 48 h  
 Method: DIN 38412  
 Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 1 mg/l  
 Exposure time: 47 h  
 Test substance: Water Accommodated Fraction  
 Method: Directive 67/548/EEC, Annex V, C.2.  
 Remarks: Based on data from similar materials  
 No toxicity at the limit of solubility
- Toxicity to algae/aquatic plants : EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
 Exposure time: 72 h  
 Test substance: Water Accommodated Fraction  
 Method: OECD Test Guideline 201  
 Remarks: Based on data from similar materials  
 No toxicity at the limit of solubility
- NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
 Exposure time: 72 h  
 Test substance: Water Accommodated Fraction  
 Method: OECD Test Guideline 201  
 Remarks: Based on data from similar materials
- Toxicity to microorganisms : EC10 (Pseudomonas putida): > 100 mg/l  
 Exposure time: 16 h  
 Test substance: Water Accommodated Fraction  
 Remarks: Based on data from similar materials

**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 %

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Exposure time: 28 d  
 Method: OECD Test Guideline 301B

**Magnesium stearate:**

Biodegradability : Result: Not biodegradable  
 Remarks: Based on data from similar materials

**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

**Magnesium stearate:**

Partition coefficient: n-octanol/water : log Pow: > 4

**Mobility in soil****Components:****Ezetimibe:**

Distribution among environmental compartments : log Koc: 4.35  
 Method: OECD Test Guideline 106

**Other adverse effects**

No data available

**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.

**14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

UN number : UN 3077  
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,



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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.

**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.

**15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

**Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.**

**Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health**

Hazardous substances that must be registered : Not applicable

**Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**

Hazardous substances approved for use : Not applicable

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Prohibited substances : Not applicable

Restricted substances : Not applicable

**Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials**

Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

**The components of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

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## 16. OTHER INFORMATION

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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

Date format : yyyy/mm/dd

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average

ID OEL / NAB : Long term exposure limit

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 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

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Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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 substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

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