

**Ezetimibe / Simvastatin Formulation**

Version 3.3      Revision Date: 05/21/2017      SDS Number: 28137-00008      Date of last issue: 05/02/2017  
Date of first issue: 11/04/2014

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**SECTION 1. IDENTIFICATION**

Product name : Ezetimibe / Simvastatin Formulation

**Manufacturer or supplier's details**

Company name of supplier : Merck & Co., Inc  
Address : 2000 Galloping Hill Road  
Kenilworth - New Jersey - USA 1685  
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



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**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with 29 CFR 1910.1200**

Combustible dust

Skin irritation : Category 2  
Specific target organ systemic toxicity - repeated exposure : Category 1 (Liver, muscle, optic nerve, Eyes)

**GHS label elements**

Hazard pictograms :  

Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.  
H315 Causes skin irritation.  
H372 Causes damage to organs (Liver, muscle, optic nerve, Eyes) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**  
P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.

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P270 Do not eat, drink or smoke when using this product.  
 P280 Wear protective gloves.

**Response:**

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.  
 P314 Get medical advice/ attention if you feel unwell.  
 P332 + P313 If skin irritation occurs: Get medical advice/ attention.  
 P362 + P364 Take off contaminated clothing and wash it before reuse.

**Disposal:**

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

**Other hazards**

Dust contact with the eyes can lead to mechanical irritation.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Hazardous ingredients**

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 10 - < 20
Ezetimibe	163222-33-1	>= 10 - < 20
Simvastatin	79902-63-9	>= 10 - < 20
Magnesium stearate	557-04-0	>= 1 - < 5

### 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 for at least 15 minutes while removing 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.

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- Most important symptoms and effects, both acute and delayed : Dust contact with the eyes can lead to mechanical irritation. Causes skin irritation. Causes damage to organs through prolonged or repeated exposure.
- 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.
- Notes to physician : Treat symptomatically and supportively.
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**SECTION 5. FIRE-FIGHTING 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 : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Fluorine compounds  
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.
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**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 containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
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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.  
 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  
 Organic peroxides  
 Explosives  
 Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL

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		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
Ezetimibe	163222-33-1	TWA	25 µg/m <sup>3</sup> (OEB 3)	Merck
		Wipe limit	250 µg/100 cm <sup>2</sup>	Merck
Simvastatin	79902-63-9	TWA	25 µg/m <sup>3</sup> (OEB 3)	Merck
		Wipe limit	250 µg/100 cm <sup>2</sup>	Merck
Magnesium stearate	557-04-0	TWA	10 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** : 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

**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 aerosols.

**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.

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Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene measures : Ensure that eye flushing systems and safety showers are located 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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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	:	powder
Color	:	No data available
Odor	:	No information 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	:	No data available
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
Relative density	:	No data available
Solubility(ies) Water solubility	:	No data available





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**Ingredients:****Cellulose:**

Result: No eye irritation

Remarks: Based on data from similar materials

**Ezetimibe:**

Species: Rabbit

Result: No eye irritation

**Simvastatin:**

Species: Rabbit

Remarks: slight irritation

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Ingredients:****Cellulose:**

Test Type: Local lymph node assay (LLNA)

Routes of exposure: Skin contact

Species: Mouse

Method: OECD Test Guideline 429

Result: negative

Remarks: Based on data from similar materials

**Ezetimibe:**

Test Type: Maximization Test

Species: Guinea pig

Result: negative

**Simvastatin:**

Test Type: Maximization Test

Species: Guinea pig

Result: Not a skin sensitizer.

**Magnesium stearate:**

Routes of exposure: Skin contact

Result: negative

**Germ cell mutagenicity**

Not classified based on available information.





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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.

### Simvastatin:

Effects on fertility : Test Type: Fertility  
 Species: Rat, male  
 Application Route: Oral  
 Fertility: LOAEL: 25 mg/kg body weight

Effects on fetal development : Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Oral  
 Embryo-fetal toxicity.: NOAEL: 25 mg/kg body weight  
 Result: No teratogenic effects., No adverse effects.

Test Type: Embryo-fetal development  
 Species: Rabbit  
 Application Route: Oral  
 Embryo-fetal toxicity.: NOAEL: 10 mg/kg body weight  
 Result: No teratogenic effects., No adverse effects.

Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Oral  
 Embryo-fetal toxicity.: LOAEL: 60 mg/kg body weight  
 Result: Teratogenic potential.  
 Remarks: Based on data from similar materials

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Causes damage to organs (Liver, muscle, optic nerve, Eyes) through prolonged or repeated exposure.

### Ingredients:

#### Simvastatin:

Target Organs: Liver, muscle, optic nerve, Eyes

Assessment: Causes damage to organs through prolonged or repeated exposure.

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**Repeated dose toxicity****Ingredients:****Cellulose:**

Species: Rat  
NOAEL: > 5,000 mg/kg  
Application Route: Ingestion  
Exposure time: 90 Days  
Remarks: Based on data from similar materials

**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

**Simvastatin:**

Species: Rat  
NOAEL: 5 mg/kg  
LOAEL: 30 mg/kg  
Application Route: Oral  
Exposure time: 14 - 104 Weeks  
Target Organs: Liver, Testes, Musculo-skeletal system, Eyes

Species: Dog  
LOAEL: 10 mg/kg  
Application Route: Oral  
Exposure time: 14 - 104 Weeks  
Target Organs: Liver, Testes, Eyes

Species: Rabbit  
NOAEL: 30 mg/kg  
LOAEL: 50 mg/kg  
Application Route: Oral

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Target Organs: Liver, Kidney

**Magnesium stearate:**

Species: Rat  
NOAEL: 5,000 mg/kg  
Application Route: Ingestion  
Exposure time: 3 Months

**Aspiration toxicity**

Not classified based on available information.

**Ingredients:****Ezetimibe:**

Not applicable

**Experience with human exposure****Ingredients:****Ezetimibe:**

Ingestion : Symptoms: Headache, Nausea, Vomiting, Diarrhea, flatulence, muscle pain, upper respiratory tract infection, Back pain, joint pain

**Simvastatin:**

Skin contact : Remarks: May produce an allergic reaction.

Ingestion : Target Organs: Liver  
Symptoms: upper respiratory tract infection, Headache, Abdominal pain, constipation, Nausea

Target Organs: Musculo-skeletal system

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Ingredients:****Cellulose:**

Toxicity to fish : LC50 (Cyprinus carpio (Carp)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: Based on data from similar materials

Toxicity to algae : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100

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mg/l  
 Exposure time: 72 h  
 Method: OECD Test Guideline 201  
 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 : 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
- 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.



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**Bioaccumulative potential****Ingredients:****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

**Simvastatin:**

Partition coefficient: n-octanol/water : log Pow: > 4.07

**Mobility in soil****Ingredients:****Ezetimibe:**

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

**Other adverse effects**

No data available

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**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.

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

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Ezetimibe, Simvastatin)  
Class : 9  
Packing group : III  
Labels : 9

**IATA-DGR**

UN/ID No. : UN 3077

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Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
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Class : 9

Packing group : III

Labels : Miscellaneous

Packing instruction (cargo aircraft) : 956

Packing instruction (passenger aircraft) : 956

### IMDG-Code

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.  
(Ezetimibe, Simvastatin)

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, Simvastatin)

Class : 9

Packing group : III

Labels : CLASS 9

ERG Code : 171

Marine pollutant : yes(Ezetimibe, Simvastatin)

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.

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## 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** : Fire Hazard  
Acute Health Hazard

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Chronic Health Hazard

**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
Ezetimibe	163222-33-1
Simvastatin	79902-63-9
Croscarmellose sodium	74811-65-7

#### California Prop. 65

WARNING! This product contains a chemical known in the State of California to cause cancer.  
 tert-Butyl-4-methoxyphenol      25013-16-5

#### California Permissible Exposure Limits for Chemical Contaminants

Cellulose	9004-34-6
Magnesium stearate	557-04-0

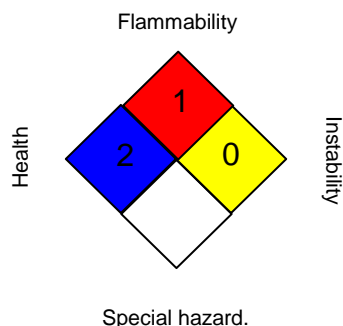
#### The ingredients of this product are reported in the following inventories:

AICS : not determined  
 DSL : not determined  
 IECSC : not determined

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA:



#### HMIS® IV:

<b>HEALTH</b>	*	<b>3</b>
<b>FLAMMABILITY</b>		<b>3</b>
<b>PHYSICAL HAZARD</b>		<b>0</b>

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

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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 substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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

Revision Date : 05/21/2017

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

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## Ezetimibe / Simvastatin Formulation

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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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