

# SAFETY DATA SHEET



## Ezetimibe Granules Formulation



Version 3.3      Revision Date: 09.04.2021      SDS Number: 1563973-00009      Date of last issue: 10.10.2020  
Date of first issue: 18.04.2017

---

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ezetimibe Granules Formulation

#### Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33rd floor  
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

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

Recommended use : Pharmaceutical

---

### 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.

---

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

# SAFETY DATA SHEET



## Ezetimibe Granules Formulation



Version 3.3      Revision Date: 09.04.2021      SDS Number: 1563973-00009      Date of last issue: 10.10.2020  
Date of first issue: 18.04.2017

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 20 -< 30
Ezetimibe	163222-33-1	>= 2.5 -< 10
Sodium n-dodecyl sulfate	151-21-3	>= 1 -< 3

### 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 : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Fluorine compounds  
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.

## Ezetimibe Granules Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.3	09.04.2021	1563973-00009	Date of first issue: 18.04.2017

---

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.

---

**6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.  
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.

---

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

---

## Ezetimibe Granules Formulation

Version 3.3      Revision Date: 09.04.2021      SDS Number: 1563973-00009      Date of last issue: 10.10.2020  
Date of first issue: 18.04.2017

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	PEL (long term)	10 mg/m <sup>3</sup>	SG OEL
		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

**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).

**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 and quantity of the hazardous substance and 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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : granular

# SAFETY DATA SHEET



## Ezetimibe Granules Formulation



Version 3.3      Revision Date: 09.04.2021      SDS Number: 1563973-00009      Date of last issue: 10.10.2020  
Date of first issue: 18.04.2017

---

Colour	:	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
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

## Ezetimibe Granules Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.3	09.04.2021	1563973-00009	Date of first issue: 18.04.2017

---

**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.

---

**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: > 2,000 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

## Ezetimibe Granules Formulation

Version 3.3      Revision Date: 09.04.2021      SDS Number: 1563973-00009      Date of last issue: 10.10.2020  
Date of first issue: 18.04.2017

---

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 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

## Ezetimibe Granules Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.3	09.04.2021	1563973-00009	Date of first issue: 18.04.2017

---

**Sodium n-dodecyl sulfate:**

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

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****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



## Ezetimibe Granules Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.3	09.04.2021	1563973-00009	Date of first issue: 18.04.2017

---

**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 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
----------------------	---	--

## Ezetimibe Granules Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.3	09.04.2021	1563973-00009	Date of first issue: 18.04.2017

---

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

**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

## Ezetimibe Granules Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.3	09.04.2021	1563973-00009	Date of first issue: 18.04.2017

---

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 yr  
 Remarks : No significant adverse effects were reported

**Sodium n-dodecyl sulfate:**

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

**Aspiration toxicity**

Not classified based on available information.

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

Not applicable

**Experience with human exposure****Components:****Ezetimibe:**

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

**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:**

## Ezetimibe Granules Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.3	09.04.2021	1563973-00009	Date of first issue: 18.04.2017

---

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

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

## Ezetimibe Granules Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.3	09.04.2021	1563973-00009	Date of first issue: 18.04.2017

---

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

**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-	:	log Pow: 0.83
---------------------------	---	---------------

## Ezetimibe Granules Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.3	09.04.2021	1563973-00009	Date of first issue: 18.04.2017

---

octanol/water

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

Distribution among environmental compartments : log K<sub>oc</sub>: 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, 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

# SAFETY DATA SHEET



## Ezetimibe Granules Formulation



Version 3.3      Revision Date: 09.04.2021      SDS Number: 1563973-00009      Date of last issue: 10.10.2020  
Date of first issue: 18.04.2017

---

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

#### Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable  
Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable  
Regulations

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

AICS : not determined

DSL : not determined

IECSC : not determined

---

## 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/>

Date format : dd.mm.yyyy

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
SG OEL : Singapore. Workplace Safety and Health Act - First Schedule Permissible Exposure Limits of Toxic Substances

ACGIH / TWA : 8-hour, time-weighted average  
SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

---

# SAFETY DATA SHEET



## Ezetimibe Granules Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.3	09.04.2021	1563973-00009	Date of first issue: 18.04.2017

---

AIIIC - Australian Inventory of Industrial Chemicals; 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 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.

SG / EN