

Ezetimibe / Simvastatin Formulation

Version 3.5 Revision Date: 09.04.2021 SDS Number: 28138-00017 Date of last issue: 16.10.2020
Date of first issue: 04.11.2014

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Trade name : Ezetimibe / Simvastatin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.
30 Hudson Street, 33rd floor
07302 Jersey City, New Jersey, U.S.A

Telephone : 551-430-6000

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number

215-631-6999

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

| | |
|--|---|
| Skin irritation, Category 2 | H315: Causes skin irritation. |
| Skin sensitisation, Category 1 | H317: May cause an allergic skin reaction. |
| Specific target organ toxicity - repeated exposure, Category 1 | H372: Causes damage to organs through prolonged or repeated exposure. |
| Long-term (chronic) aquatic hazard, Category 2 | H411: Toxic to aquatic life with long lasting effects. |

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :



Signal word : Danger

Hazard statements : H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H372 Causes damage to organs through prolonged or repeated exposure.
H411 Toxic to aquatic life with long lasting effects.

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Precautionary statements : **Prevention:**
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves.

Response:
P314 Get medical advice/ attention if you feel unwell.
P391 Collect spillage.

Hazardous components which must be listed on the label:
Simvastatin

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
Dust contact with the eyes can lead to mechanical irritation.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients**3.2 Mixtures****Components**

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|---------------|---|---|--------------------------|
| Ezetimibe | 163222-33-1 | Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 1 | >= 10 - < 20 |
| Simvastatin | 79902-63-9 | Skin Irrit. 2; H315 Skin Sens. 1; H317 STOT RE 1; H372 (Liver, muscle, optic nerve, Eye) Aquatic Chronic 2; H411 | >= 10 - < 20 |

For explanation of abbreviations see section 16.

SECTION 4: First aid measures**4.1 Description of 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.

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- 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).
- 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.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : Causes skin irritation.
May cause an allergic skin reaction.
Causes damage to organs through prolonged or repeated exposure.
- Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.
-

SECTION 5: Firefighting measures**5.1 Extinguishing media**

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

- 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_x)

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Fluorine compounds
Metal oxides

5.3 Advice for firefighters

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

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

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

6.2 Environmental precautions

- 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.

6.3 Methods and material for containment and cleaning up

- Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.

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- Local/Total ventilation : Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Advice on safe handling : Use only with adequate ventilation.
Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Wash skin thoroughly after handling.
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.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.
- 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. Contaminated work clothing should not be allowed out of the workplace.
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.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.
- Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

- Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|--|-----------|---------------------------------|----------------------|--------|
| Cellulose | 9004-34-6 | TWA OEL-RL (Respirable dust) | 5 mg/m ³ | ZA OEL |
| Further information: Recommended Limit | | | | |
| | | TWA OEL-RL | 10 mg/m ³ | ZA OEL |

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| | | | | |
|-------------|--|-----------------------|------------------------------|----------|
| | | (inhalable dust) | | |
| | Further information: Recommended Limit | | | |
| | | STEL OEL-RL (Dust) | 20 mg/m ³ | ZA OEL |
| | Further information: Recommended Limit | | | |
| Ezetimibe | 163222-33-1 | TWA | 25 µg/m ³ (OEB 3) | Internal |
| | | Wipe limit | 250 µg/100 cm ² | Internal |
| Simvastatin | 79902-63-9 | TWA | 25 µg/m ³ (OEB 3) | Internal |
| | Further information: DSEN | | | |
| | | Wipe limit | 250 µg/100 cm ² | Internal |

8.2 Exposure controls

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

- 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.
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- 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.
Use appropriate degowning techniques to remove potentially contaminated clothing.
- 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 (P)

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

- Appearance : powder
- Colour : No data available
- Odour : No data available

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| | | |
|--|---|---|
| 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 | : | No data available |
| Evaporation rate | : | No data available |
| Flammability (solid, gas) | : | May form explosive dust-air mixture during processing, handling or other means. |
| 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 |
| 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. |

9.2 Other information

| | | |
|------------------------|---|-------------------|
| Flammability (liquids) | : | No data available |
| Molecular weight | : | No data available |
| Particle size | : | No data available |

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

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10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information**11.1 Information on toxicological effects**

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

Acute toxicity

Not classified based on available information.

Components:**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

Simvastatin:

Acute oral toxicity : LD50 (Rat): 5.000 mg/kg
LD50 (Mouse): 3.800 mg/kg

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Skin corrosion/irritation

Causes skin irritation.

Components:**Ezetimibe:**

| | | |
|---------|---|--------------------|
| Species | : | Rabbit |
| Result | : | No skin irritation |

Simvastatin:

| | | |
|---------|---|--------------------------|
| Species | : | Rabbit |
| Remarks | : | Moderate skin irritation |

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Ezetimibe:**

| | | |
|---------|---|-------------------|
| Species | : | Rabbit |
| Result | : | No eye irritation |

Simvastatin:

| | | |
|---------|---|-------------------|
| Species | : | Rabbit |
| Remarks | : | slight irritation |

Respiratory or skin sensitisation**Skin sensitisation**

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:**Ezetimibe:**

| | | |
|-----------|---|-------------------|
| Test Type | : | Maximisation Test |
| Species | : | Guinea pig |
| Result | : | negative |

Simvastatin:

| | | |
|------------|---|---|
| Assessment | : | Probability or evidence of skin sensitisation in humans |
| Result | : | positive |

Germ cell mutagenicity

Not classified based on available information.

Components:**Ezetimibe:**

| | | |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) |
|-----------------------|---|--|

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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

Simvastatin:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Alkaline elution assay
Result: negative

Test Type: Chromosomal aberration
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Germ cell mutagenicity- Assessment : Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity

Not classified based on available information.

Components:**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

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Simvastatin:

Species : Mouse
 Application Route : Oral
 Exposure time : < 92 weeks
 Target Organs : Harderian gland
 Tumor Type : Liver, Lungs
 Remarks : The significance of these findings for humans is not certain.

Species : Rat
 Application Route : Oral
 Exposure time : 2 Years
 Tumor Type : Liver, Thyroid
 Remarks : The significance of these findings for humans is not certain.

Reproductive toxicity

Not classified based on available information.

Components:**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

Simvastatin:

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

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

Test Type: Embryo-foetal development
 Species: Rabbit
 Application Route: Oral

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Embryo-foetal toxicity: NOAEL: 10 mg/kg body weight
Result: No teratogenic effects, No adverse effects

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Embryo-foetal 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 through prolonged or repeated exposure.

Components:**Simvastatin:**

Target Organs : Liver, muscle, optic nerve, Eye
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****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

Simvastatin:

Species : Rat

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

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

Species : Rabbit
NOAEL : 30 mg/kg
LOAEL : 50 mg/kg
Application Route : Oral
Target Organs : Liver, Kidney

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

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

SECTION 12: Ecological information**12.1 Toxicity****Components:****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

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- 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 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
- Toxicity to fish (Chronic toxicity) : NOEC: 0,051 mg/l
Exposure time: 33 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210
- NOEC: 4 mg/l
Exposure time: 7 d
Species: Cyprinodon variegatus (sheepshead minnow)
Remarks: No toxicity at the limit of solubility
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,282 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Remarks: No toxicity at the limit of solubility
- M-Factor (Chronic aquatic toxicity) : 1
- Simvastatin:**
- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 2,91 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 3,5 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

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| | | |
|----------------------------------|---|--|
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 25 mg/l Exposure time: 96 h |
| | | NOEC (Pseudokirchneriella subcapitata (green algae)): 25 mg/l Exposure time: 96 h |
| Toxicity to microorganisms | : | EC50 : > 30 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 |
| | | NOEC : 21 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 |

12.2 Persistence and degradability**Components:****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 |
|--------------------|---|--|

Simvastatin:

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|------------------|---|----------------------------|
| Biodegradability | : | Result: rapidly degradable |
|------------------|---|----------------------------|

| | | |
|--------------------|---|-------------------------|
| Stability in water | : | Hydrolysis: 50 %(3,2 d) |
|--------------------|---|-------------------------|

12.3 Bioaccumulative potential**Components:****Ezetimibe:**

| | | |
|-----------------|---|---|
| Bioaccumulation | : | Species: Lepomis macrochirus (Bluegill sunfish) Exposure time: 97 d Bioconcentration factor (BCF): 173 Method: OECD Test Guideline 305 |
|-----------------|---|---|

| | | |
|--|---|---------------|
| Partition coefficient: n-octanol/water | : | log Pow: 4,36 |
|--|---|---------------|

Simvastatin:

| | | |
|--|---|-----------------|
| Partition coefficient: n-octanol/water | : | log Pow: > 4,07 |
|--|---|-----------------|

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

Distribution among environmental compartments : log K_{oc}: 4,35
Method: OECD Test Guideline 106

12.5 Results of PBT and vPvB assessment**Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects**Product:**

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information**14.1 UN number**

ADN : UN 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

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(Ezetimibe, Simvastatin)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Ezetimibe, Simvastatin)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Ezetimibe, Simvastatin)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Ezetimibe, Simvastatin)

IATA : Environmentally hazardous substance, solid, n.o.s.
(Ezetimibe, Simvastatin)

14.3 Transport hazard class(es)

ADN : 9

ADR : 9

RID : 9

IMDG : 9

IATA : 9

14.4 Packing group

ADN
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

ADR
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

IMDG
Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)
Packing instruction (cargo aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

IATA (Passenger)

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| | | |
|--|---|---------------|
| Packing instruction (passenger aircraft) | : | 956 |
| Packing instruction (LQ) | : | Y956 |
| Packing group | : | III |
| Labels | : | Miscellaneous |

14.5 Environmental hazards**ADN**

| | | |
|---------------------------|---|-----|
| Environmentally hazardous | : | yes |
|---------------------------|---|-----|

ADR

| | | |
|---------------------------|---|-----|
| Environmentally hazardous | : | yes |
|---------------------------|---|-----|

RID

| | | |
|---------------------------|---|-----|
| Environmentally hazardous | : | yes |
|---------------------------|---|-----|

IMDG

| | | |
|------------------|---|-----|
| Marine pollutant | : | yes |
|------------------|---|-----|

IATA (Passenger)

| | | |
|---------------------------|---|-----|
| Environmentally hazardous | : | yes |
|---------------------------|---|-----|

IATA (Cargo)

| | | |
|---------------------------|---|-----|
| Environmentally hazardous | : | yes |
|---------------------------|---|-----|

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

| | | |
|---------|---|---|
| Remarks | : | Not applicable for product as supplied. |
|---------|---|---|

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

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

| | | |
|------|---|----------------|
| AICS | : | not determined |
|------|---|----------------|

| | | |
|-----|---|----------------|
| DSL | : | not determined |
|-----|---|----------------|

| | | |
|-------|---|----------------|
| IECSC | : | not determined |
|-------|---|----------------|

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

| | | |
|-------------------|---|--|
| Other information | : | 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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Full text of H-Statements

H315 : Causes skin irritation.
H317 : May cause an allergic skin reaction.
H372 : Causes damage to organs through prolonged or repeated exposure.
H410 : Very toxic to aquatic life with long lasting effects.
H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Chronic : Long-term (chronic) aquatic hazard
Skin Irrit. : Skin irritation
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit
ZA OEL / STEL OEL-RL : Short term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; 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

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/>

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Classification of the mixture:

| | |
|-------------------|------|
| Skin Irrit. 2 | H315 |
| Skin Sens. 1 | H317 |
| STOT RE 1 | H372 |
| Aquatic Chronic 2 | H411 |

Classification procedure:

| |
|--------------------|
| Calculation method |
| Calculation method |
| Calculation method |
| Calculation method |

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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