# SAFETY DATA SHEET

# Simvastatin Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 26.09.2023 |
|---|---|---|---|
| 6.0 | 06.04.2024 | 24383-00022 | Date of first issue: 21.10.2014 |

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier

Trade name : Simvastatin Formulation

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

Use of the Substance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

### 1.3 Details of the supplier of the safety data sheet

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

Telephone : +1-551-430-6000

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

### 1.4 Emergency telephone number

+1-215-631-6999

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008)**

| | |
|---|---|
| Skin sensitisation, Category 1 | H317: May cause an allergic skin reaction. |
| Specific target organ toxicity - repeated exposure, Category 2 | H373: May cause damage to organs through prolonged or repeated exposure. |
| Long-term (chronic) aquatic hazard, Category 3 | H412: Harmful to aquatic life with long lasting effects. |

### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :

Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.
H373 May cause damage to organs through prolonged or repeated exposure.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements :

**Prevention:**

P260 Do not breathe dust.
P273 Avoid release to the environment.
P280 Wear protective gloves.

**Response:**

P314 Get medical advice/ attention if you feel unwell.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

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.<br>EC-No.<br>Index-No.<br>Registration number | Classification | Concentration (% w/w) |
|---|---|---|---|
| Simvastatin | 79902-63-9 | Skin Irrit. 2; H315<br>Skin Sens. 1; H317<br>STOT RE 1; H372 (Liver, muscle, optic nerve, Eye)<br>Aquatic Chronic 2; H411 | >= 2,5 - < 10 |
| Citric acid monohydrate | 5949-29-1 | Eye Irrit. 2; H319<br>STOT SE 3; H335 | >= 1 - < 10 |
| Substances with a workplace exposure limit : | | | |
| Ascorbic acid | 50-81-7<br>200-066-2 | | >= 1 - < 10 |

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.

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.

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.

### 4.2 Most important symptoms and effects, both acute and delayed

Risks : May cause an allergic skin reaction.
May cause 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.<br>Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides |

### 5.3 Advice for firefighters

| | | |
|---|---|---|
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

| | | |
|---|---|---|
| Personal precautions | : | Use personal protective equipment.<br>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.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>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.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>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.<br>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.<br>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.<br>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.<br>Do not breathe dust.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>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.<br>Wash contaminated clothing before re-use.<br>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:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>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 |
|---|---|---|---|---|
| Simvastatin | 79902-63-9 | TWA | 25 µg/m3 (OEB 3) | Internal |
| | Further information: DSEN | | | |
| | | Wipe limit | 250 µg/100 cm² | Internal |
| Starch | 9005-25-8 | OEL-RL | 10 mg/m3 | ZA OEL |
| | Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents | | | |
| Cellulose | 9004-34-6 | OEL-RL | 10 mg/m3 | ZA OEL |
| | Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents | | | |
| Ascorbic acid | 50-81-7 | TWA | 5000 µg/m3 (OEB 1) | Internal |

**Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:**

| Substance name | Environmental Compartment | Value |
|---|---|---|
| Citric acid monohydrate | Fresh water | 0,44 mg/l |
| | Marine water | 0,044 mg/l |
| | Sewage treatment plant | 1000 mg/l |
| | Fresh water sediment | 34,6 mg/kg dry weight (d.w.) |
| | Marine sediment | 3,46 mg/kg dry weight (d.w.) |
| | Soil | 33,1 mg/kg dry weight (d.w.) |

### 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/face 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.<br>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 | : | odourless |
| 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 | : | Not applicable |
| 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 | : | Not applicable |
| Relative vapour density | : | Not applicable |
| Relative density | : | No data available |
| Density | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity | | |

| | | |
|---|---|---|
| Viscosity, kinematic | : | Not applicable |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |

**9.2 Other information**

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

## SECTION 10: Stability and reactivity

**10.1 Reactivity**

Not classified as a reactivity hazard.

**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.<br>Can react with strong oxidizing agents. |

**10.4 Conditions to avoid**

| | | |
|---|---|---|
| Conditions to avoid | : | Heat, flames and sparks.<br>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<br>Skin contact<br>Ingestion<br>Eye contact |

**Acute toxicity**

Not classified based on available information.

**Components:**

**Simvastatin:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 5.000 mg/kg<br><br>LD50 (Mouse): 3.800 mg/kg |

**Citric acid monohydrate:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Mouse): 5.400 mg/kg |
| Acute dermal toxicity | : | LD50 (Rat): > 2.000 mg/kg<br>Method: OECD Test Guideline 402<br>Assessment: The substance or mixture has no acute dermal toxicity |

**Ascorbic acid:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 11.900 mg/kg |

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**Simvastatin:**

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

**Citric acid monohydrate:**

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

**Ascorbic acid:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Method | : | OECD Test Guideline 404 |
| Result | : | No skin irritation |

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**Simvastatin:**

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

**Citric acid monohydrate:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | Irritation to eyes, reversing within 21 days |

**Ascorbic acid:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Method | : | OECD Test Guideline 405 |
| Result | : | No eye irritation |

**Respiratory or skin sensitisation**

**Skin sensitisation**

May cause an allergic skin reaction.

**Respiratory sensitisation**

Not classified based on available information.

**Components:**

**Simvastatin:**

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

**Ascorbic acid:**

| | | |
|---|---|---|
| Test Type | : | Maurer optimisation test |
| Exposure routes | : | Skin contact |
| Species | : | Guinea pig |
| Result | : | negative |

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**Simvastatin:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: Alkaline elution assay<br>Result: negative<br><br>Test Type: Chromosomal aberration<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Micronucleus test<br>Species: Mouse<br>Application Route: Oral<br>Result: negative |
| Germ cell mutagenicity- Assessment | : | Weight of evidence does not support classification as a germ cell mutagen. |

**Citric acid monohydrate:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: in vitro micronucleus test<br>Result: positive<br><br>Test Type: Bacterial reverse mutation assay (AMES) |

Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative

**Ascorbic acid:**

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

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

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:**

**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. |

**Ascorbic acid:**

| | | |
|---|---|---|
| Species | : | Mouse |
| Application Route | : | Ingestion |
| Exposure time | : | 2 Years |
| Result | : | negative |

**Reproductive toxicity**

Not classified based on available information.

**Components:**

**Simvastatin:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Fertility<br>Species: Rat, male<br>Application Route: Oral<br>Fertility: LOAEL: 25 mg/kg body weight |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Oral<br>Embryo-foetal toxicity: NOAEL: 25 mg/kg body weight<br>Result: No teratogenic effects, No adverse effects<br><br>Test Type: Embryo-foetal development<br>Species: Rabbit<br>Application Route: Oral<br>Embryo-foetal toxicity: NOAEL: 10 mg/kg body weight<br>Result: No teratogenic effects, No adverse effects<br><br>Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Oral<br>Embryo-foetal toxicity: LOAEL: 60 mg/kg body weight<br>Result: Teratogenic potential<br>Remarks: Based on data from similar materials |

**Citric acid monohydrate:**

| | | |
|---|---|---|
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

**Ascorbic acid:**

| | | |
|---|---|---|
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

**STOT - single exposure**

Not classified based on available information.

**Components:**

**Citric acid monohydrate:**

| | | |
|---|---|---|
| Assessment | : | May cause respiratory irritation. |

**STOT - repeated exposure**

May cause 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:**

**Simvastatin:**

| | | |
|---|---|---|
| Species | : | Rat |
| 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 |

**Citric acid monohydrate:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 4.000 mg/kg |
| LOAEL | : | 8.000 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 10 Days |

**Ascorbic acid:**

| | | |
|---|---|---|
| Species | : | Rat, male |
| NOAEL | : | >= 8.100 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 13 Weeks |

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure**

**Components:**

**Simvastatin:**

| | | |
|---|---|---|
| Skin contact | : | Remarks: May produce an allergic reaction. |

| | | |
|---|---|---|
| Ingestion | : | Target Organs: Liver<br>Symptoms: upper respiratory tract infection, Headache, Abdominal pain, constipation, Nausea<br>Target Organs: Musculo-skeletal system |

## SECTION 12: Ecological information

### 12.1 Toxicity

**Components:**

**Simvastatin:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): 2,91 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203 |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 3,5 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 25 mg/l<br>Exposure time: 96 h<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 25 mg/l<br>Exposure time: 96 h |
| Toxicity to microorganisms | : | EC50 : > 30 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209<br><br>NOEC : 21 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209 |

**Citric acid monohydrate:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 1.535 mg/l<br>Exposure time: 24 h |

**Ascorbic acid:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 1.020 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203 |
| Toxicity to microorganisms | : | EC50 : 140 mg/l<br>Exposure time: 16 h<br>Method: DIN 38 412 Part 8 |

## 12.2 Persistence and degradability

**Components:**

**Simvastatin:**

| | | |
|---|---|---|
| Biodegradability | : | Result: rapidly degradable |
| Stability in water | : | Hydrolysis: 50 %(3,2 d) |

**Citric acid monohydrate:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 97 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301B |

**Ascorbic acid:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 97 %<br>Exposure time: 5 d<br>Method: OECD Test Guideline 302 |

## 12.3 Bioaccumulative potential

**Components:**

**Simvastatin:**

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

**Citric acid monohydrate:**

| | | |
|---|---|---|
| Partition coefficient: n-octanol/water | : | log Pow: -1,72 |

**Ascorbic acid:**

| | | |
|---|---|---|
| Partition coefficient: n-octanol/water | : | log Pow: -1,85 |

## 12.4 Mobility in soil

No data available

## 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 poten- | : | The substance/mixture does not contain components consid- |

tial | ered 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.
Do not dispose of waste into sewer.

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** : Not regulated as a dangerous good

**ADR** : Not regulated as a dangerous good

**RID** : Not regulated as a dangerous good

**IMDG** : Not regulated as a dangerous good

**IATA** : Not regulated as a dangerous good

### 14.2 UN proper shipping name

**ADN** : Not regulated as a dangerous good

**ADR** : Not regulated as a dangerous good

**RID** : Not regulated as a dangerous good

**IMDG** : Not regulated as a dangerous good

**IATA** : Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

**ADN** : Not regulated as a dangerous good

**ADR** : Not regulated as a dangerous good

**RID** : Not regulated as a dangerous good

**IMDG** : Not regulated as a dangerous good

**IATA** : Not regulated as a dangerous good

### 14.4 Packing group

**ADN** : Not regulated as a dangerous good

**ADR** : Not regulated as a dangerous good

| | | |
|---|---|---|
| **RID** | : | Not regulated as a dangerous good |
| **IMDG** | : | Not regulated as a dangerous good |
| **IATA (Cargo)** | : | Not regulated as a dangerous good |
| **IATA (Passenger)** | : | Not regulated as a dangerous good |

**14.5 Environmental hazards**

Not regulated as a dangerous good

**14.6 Special precautions for user**

Not applicable

**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.

**Full text of H-Statements**

| | | |
|---|---|---|
| H315 | : | Causes skin irritation. |
| H317 | : | May cause an allergic skin reaction. |
| H319 | : | Causes serious eye irritation. |
| H335 | : | May cause respiratory irritation. |
| H372 | : | Causes damage to organs through prolonged or repeated exposure. |
| H411 | : | Toxic to aquatic life with long lasting effects. |

**Full text of other abbreviations**

| | | |
|---|---|---|
| Aquatic Chronic | : | Long-term (chronic) aquatic hazard |
| Eye Irrit. | : | Eye irritation |
| Skin Irrit. | : | Skin irritation |
| Skin Sens. | : | Skin sensitisation |
| STOT RE | : | Specific target organ toxicity - repeated exposure |
| STOT SE | : | Specific target organ toxicity - single exposure |

| | | |
|---|---|---|
| ZA OEL | : | South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits |
| ZA OEL / OEL-RL | : | Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts) |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - 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; TECI - Thailand Existing Chemicals 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**

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|---|---|---|
| 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/ |

| **Classification of the mixture:** | | **Classification procedure:** |
|---|---|---|
| Skin Sens. 1 | H317 | Calculation method |
| STOT RE 2 | H373 | Calculation method |
| Aquatic Chronic 3 | H412 | Calculation method |

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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

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