Simvastatin Formulation



Version **Revision Date:** SDS Number: Date of last issue: 24.04.2019 13.09.2019 24383-00014 Date of first issue: 21.10.2014 3.2

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 Sub-: Pharmaceutical

stance/Mixture

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 : 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 sensitisation, Category 1 H317: May cause an allergic skin reaction.

Specific target organ toxicity - repeated H373: May cause damage to organs through pro-

exposure, Category 2 longed or repeated exposure.

Long-term (chronic) aquatic hazard, Cat-H412: Harmful to aquatic life with long lasting ef-

egory 3 fects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) Hazard pictograms

Signal word Warning

Hazard statements May cause an allergic skin reaction. H317

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.

Simvastatin Formulation



Version Revision Date: SDS Number: Date of last issue: 24.04.2019
3.2 13.09.2019 24383-00014 Date of first issue: 21.10.2014

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

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)
Simvastatin	79902-63-9	Skin Irrit.2; H315 Skin Sens.1; H317 STOT RE1; H372 Aquatic Chronic2; H411	>= 2,5 - < 10
Citric acid monohydrate	5949-29-1	Eye Irrit.2; H319	>= 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 ad-

vice 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.

Simvastatin Formulation



Version **Revision Date:** SDS Number: Date of last issue: 24.04.2019 13.09.2019 24383-00014 Date of first issue: 21.10.2014 3.2

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.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon 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 meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

Simvastatin Formulation



Version Revision Date: SDS Number: Date of last issue: 24.04.2019
3.2 13.09.2019 24383-00014 Date of first issue: 21.10.2014

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

Follow safe handling advice and personal protective equip-

ment recommendations.

6.2 Environmental precautions

Environmental precautions : Discharge into the environment must be avoided.

Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable con-

tainer 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 deter-

mine 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.

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 as-

sessment

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.





Version Revision Date: SDS Number: Date of last issue: 24.04.2019
3.2 13.09.2019 24383-00014 Date of first issue: 21.10.2014

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. Wash contami-

nated 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		
Simvastatin	79902-63-9	TWA	25 μg/m3 (OEB 3)	Internal		
Further information	DSEN					
		Wipe limit	250 μg/100 cm ²	Internal		
Starch	9005-25-8	TWA OEL-RL (Respirable dust)	5 mg/m3	ZA OEL		
Further information	Recommended Limit					
		TWA OEL-RL (inhalable dust)	10 mg/m3	ZA OEL		
Further information	Recommende	Recommended Limit				
Cellulose	9004-34-6	TWA OEL-RL (Respirable dust)	5 mg/m3	ZA OEL		
Further information	Recommended Limit					
		TWA OEL-RL (inhalable dust)	10 mg/m3	ZA OEL		
Further information	Recommended Limit					
		STEL OEL-RL (Dust)	20 mg/m3	ZA OEL		
Further information	Recommended Limit					

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





Version Revision Date: SDS Number: Date of last issue: 24.04.2019
3.2 13.09.2019 24383-00014 Date of first issue: 21.10.2014

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 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 expo-

sure assessment demonstrates exposures outside the rec-

ommended 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

Simvastatin Formulation



Version Revision Date: SDS Number: Date of last issue: 24.04.2019
3.2 13.09.2019 24383-00014 Date of first issue: 21.10.2014

Initial boiling point and boiling

range

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling or other means.

No data available

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- : Not applicable

octanol/water

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

Simvastatin Formulation



Version Revision Date: SDS Number: Date of last issue: 24.04.2019
3.2 13.09.2019 24383-00014 Date of first issue: 21.10.2014

Hazardous reactions : May form explosive dust-air mixture during processing, han-

dling 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 : Inhalation exposure Skin contact

Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Simvastatin:

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

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

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

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

Simvastatin Formulation



Version Revision Date: SDS Number: Date of last issue: 24.04.2019
3.2 13.09.2019 24383-00014 Date of first issue: 21.10.2014

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

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

Germ cell mutagenicity

Not classified based on available information.

Components:

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- As-

sessment

Weight of evidence does not support classification as a germ

cell mutagen.

Simvastatin Formulation



Version Revision Date: SDS Number: Date of last issue: 24.04.2019
3.2 13.09.2019 24383-00014 Date of first issue: 21.10.2014

Citric acid monohydrate:

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

Result: negative

Test Type: in vitro micronucleus test

Result: positive

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

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.

Reproductive toxicity

Not classified based on available information.

Components:

Simvastatin:

Effects on fertility : Test Type: Fertility

Species: Rat, male Application Route: Oral

Fertility: LOAEL: 25 mg/kg body weight

Effects on foetal develop-

ment

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





Version Revision Date: SDS Number: Date of last issue: 24.04.2019
3.2 13.09.2019 24383-00014 Date of first issue: 21.10.2014

Application Route: Oral

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

Citric acid monohydrate:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

STOT - single exposure

Not classified based on available information.

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



Simvastatin Formulation

⇔ ORGANON

Version Revision Date: SDS Number: Date of last issue: 24.04.2019
3.2 13.09.2019 24383-00014 Date of first issue: 21.10.2014

Citric acid monohydrate:

Species : Rat

NOAEL : 4.000 mg/kg LOAEL : 8.000 mg/kg Application Route : Ingestion Exposure time : 10 Days

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

Symptoms: upper respiratory tract infection, Headache, Ab-

dominal pain, constipation, Nausea 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

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

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

Simvastatin Formulation



Version Revision Date: SDS Number: Date of last issue: 24.04.2019
3.2 13.09.2019 24383-00014 Date of first issue: 21.10.2014

Citric acid monohydrate:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 1.535 mg/l

Exposure time: 24 h

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.

Biodegradation: 97 % Exposure time: 28 d

Method: OECD Test Guideline 301B

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

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

Simvastatin Formulation



Version Revision Date: SDS Number: Date of last issue: 24.04.2019
3.2 13.09.2019 24383-00014 Date of first issue: 21.10.2014

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

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.

H372 : Causes damage to organs through prolonged or repeated

exposure.

H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations





Version Revision Date: SDS Number: Date of last issue: 24.04.2019
3.2 13.09.2019 24383-00014 Date of first issue: 21.10.2014

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

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: AICS - Australian Inventory of Chemical Substances; 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 Agen-

cy, 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





Version Revision Date: SDS Number: Date of last issue: 24.04.2019
3.2 13.09.2019 24383-00014 Date of first issue: 21.10.2014

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.

ZA / EN