Simvastatin Formulation



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 24345-00023
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SECTION 1. IDENTIFICATION

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33nd floor

Jersey City, New Jersey, U.S.A 07302

Telephone : 1-551-430-6000

Emergency telephone : 1-215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Skin corrosion/irritation : Category 3

Skin sensitization : Category 1

Specific target organ toxicity - :

repeated exposure

Category 2 (Liver, muscle, optic nerve, Eye)

Short-term (acute) aquatic

hazard

Category 3

Long-term (chronic) aquatic

hazard

Category 3

GHS label elements

Hazard pictograms





Signal Word : Warning

Hazard Statements : H316 Causes mild skin irritation.

H317 May cause an allergic skin reaction.

H373 May cause damage to organs (Liver, muscle, optic nerve,

Eye) through prolonged or repeated exposure. H412 Harmful to aquatic life with long lasting effects.

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Precautionary Statements : Prevention:

P260 Do not breathe dust.

P272 Contaminated work clothing should not be allowed out of

the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water. P314 Get medical advice/ attention if you feel unwell.

P333 + P313 If skin irritation or rash occurs: Get medical ad-

vice/ attention.

P362 + P364 Take off contaminated clothing and wash it before

reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.

May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	
Simvastatin	79902-63-9	>= 5 -< 10	
Starch	9005-25-8	>= 5 -< 10	
Cellulose	9004-34-6	>= 1 -< 5	
Ascorbic acid	50-81-7	>= 1 -< 5	
Citric acid monohydrate	5949-29-1	>= 1 -< 5	
Titanium dioxide	13463-67-7	>= 0,1 -< 1	

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

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, DO NOT induce vomiting.

Get medical attention if symptoms occur.





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Rinse mouth thoroughly with water.

Most important symptoms

Protection of first-aiders

and effects, both acute and

delayed

Causes mild skin irritation. 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. First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical None known.

Unsuitable extinguishing

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

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

Evacuate area.

Special protective equipment :

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions Avoid release to the environment.

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

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up Sweep up or vacuum up spillage and collect in suitable

container for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are





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released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation. Advice on safe handling : Do not get on skin or clothing.

Do not breathe dust. Do not swallow. Avoid contact with eyes.

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.

Conditions for safe storage : Keep in properly labeled containers.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	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	CMP	10 mg/m ³	AR OEL	
	Further information: A4 - Not classifiable as a human carcinogen				
		TWA	10 mg/m ³	ACGIH	
Cellulose	9004-34-6	CMP	10 mg/m ³	AR OEL	





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		TWA	10 mg/m ³	ACGIH		
Ascorbic acid	50-81-7	TWA	5000 μg/m3 (OEB	Internal		
			1)			
Titanium dioxide	13463-67-7	CMP	10 mg/m ³	AR OEL		
	Further inform	Further information: A4 - Not classifiable as a human carcinogen				

Engineering measures : All engineering controls should be implemented by facility

design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face

containment devices). Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Filter type Hand protection

Particulates type

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Color : No data available

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Odor : odorless

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : Not applicable

Evaporation rate : Not applicable

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

handling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : Not applicable

Relative vapor 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

Autoignition 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.

Particle characteristics

Particle size : No data available

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SECTION 10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions.

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing,

handling or other means.

Can react with strong oxidizing agents.

Conditions to avoid Heat, flames and sparks.

Avoid dust formation. Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation 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

Starch:

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

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

Cellulose:

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

Acute inhalation toxicity LC50 (Rat): > 5.8 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

LD50 (Rabbit): > 2.000 mg/kg Acute dermal toxicity

Ascorbic acid:

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

Citric acid monohydrate:

Acute oral toxicity LD50 (Mouse): 5.400 mg/kg



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Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Titanium dioxide:

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

Acute inhalation toxicity : LC50 (Rat): > 6,82 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Skin corrosion/irritation

Causes mild skin irritation.

Components:

Simvastatin:

Species : Rabbit

Remarks : Moderate skin irritation

Ascorbic acid:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Citric acid monohydrate:

Species : Rabbit

Result : No skin irritation

Titanium dioxide:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Simvastatin:

Species : Rabbit

Remarks : slight irritation

Starch:

Species : Rabbit

Result : No eye irritation



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Ascorbic acid:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Citric acid monohydrate:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Titanium dioxide:

Species : Rabbit

Result : No eye irritation

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Components:

Simvastatin:

Assessment : Probability or evidence of skin sensitization in humans

Result : positive

Starch:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Ascorbic acid:

Test Type : Maurer optimisation test

Routes of exposure : Skin contact Species : Guinea pig Result : negative

Titanium dioxide:

Test Type : Local lymph node assay (LLNA)

Routes of exposure : Skin contact Species : Mouse Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Simvastatin:





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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.

Starch:

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

Result: negative

Cellulose:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

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



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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

Titanium dioxide:

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

Result: negative

Genotoxicity in vivo Test Type: In vivo micronucleus test

> Species: Mouse 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.

Cellulose:

Species Rat **Application Route** Ingestion Exposure time 72 weeks Result negative

Ascorbic acid:

Species Mouse Application Route Ingestion

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Exposure time : 2 Years
Result : negative

Titanium dioxide:

Species : Rat

Application Route : inhalation (dust/mist/fume)

Exposure time : 2 Years

Method : OECD Test Guideline 453

Result : positive

Remarks : The mechanism or mode of action may not be relevant in hu-

mans.

Carcinogenicity - Assess-

ment

Limited evidence of carcinogenicity in inhalation studies with

animals.

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 fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

Embryo-fetal toxicity.: NOAEL: 25 mg/kg body weight Result: No teratogenic effects., No adverse effects.

Test Type: Embryo-fetal development

Species: Rabbit Application Route: Oral

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

Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

Embryo-fetal toxicity .: LOAEL: 60 mg/kg body weight

Result: Teratogenic potential.

Remarks: Based on data from similar materials

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Effects on fetal development : Test Type: Fertility/early embryonic development

Species: Rat



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Application Route: Ingestion

Result: negative

Ascorbic acid:

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion

Result: negative

Citric acid monohydrate:

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion

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 (Liver, muscle, optic nerve, Eye) 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



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

Target Organs : Liver, Kidney

Starch:

Species : Rat

NOAEL : >= 2.000 mg/kg
Application Route : Skin contact
Exposure time : 28 Days

Method : OECD Test Guideline 410

Cellulose:

Species : Rat

NOAEL : >= 9.000 mg/kg

Application Route : Ingestion Exposure time : 90 Days

Ascorbic acid:

Species : Rat, male

NOAEL : >= 8.100 mg/kg

Application Route : Ingestion

Exposure time : 13 Weeks

Citric acid monohydrate:

Species : Rat

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

Titanium dioxide:

Species : Rat

NOAEL : 24.000 mg/kg
Application Route : Ingestion
Exposure time : 28 Days

Species : Rat NOAEL : 10 mg/m³

Application Route : inhalation (dust/mist/fume)

Exposure time : 2 y

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Simvastatin:

Skin contact : Remarks: May produce an allergic reaction.

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Ingestion : Target Organs: Liver

Symptoms: upper respiratory tract infection, Headache, Ab-

dominal pain, constipation, Nausea Target Organs: Musculo-skeletal system

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

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/i

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

Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Ascorbic acid:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 1.020 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to microorganisms : EC50: 140 mg/l

Exposure time: 16 h Method: DIN 38 412 Part 8

Citric acid monohydrate:



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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

Titanium dioxide:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Skeletonema costatum (marine diatom)): > 10.000 mg/l

Exposure time: 72 h

Toxicity to microorganisms : EC50: > 1.000 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Persistence and degradability

Components:

Simvastatin:

Biodegradability : Result: rapidly degradable

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

Cellulose:

Biodegradability : Result: Readily biodegradable.

Ascorbic acid:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 97 % Exposure time: 5 d

Method: OECD Test Guideline 302

Citric acid monohydrate:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 97 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Bioaccumulative potential

Components:

Simvastatin:

Partition coefficient: n- : log Pow: > 4,07

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octanol/water

Ascorbic acid:

Partition coefficient: n-

octanol/water

log Pow: -1,85

Citric acid monohydrate:

Partition coefficient: n-

octanol/water

log Pow: -1,72

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Argentina. Carcinogenic Substances and Agents : Not applicable

Registry.

Control of precursors and essential chemicals for the : Not applicable

preparation of drugs.

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

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AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

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Further information

Sources of key data used to compile the Material Safety

compile the Material 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/

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average AR OEL / CMP : TLV (Threshold Limit Value)

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China: IMDG - International Maritime Dangerous Goods: IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation. Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System





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