

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Trade name : Forma Shine 100
Revision date : 17.05.2023
Print date : 23.05.2023

Version (Revision) : 1.0.1 (1.0.0)

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

1.1 Product identifier

Forma Shine 100

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

Relevant identified uses

PC 35 - Washing and cleaning products

Sectors of use [SU]

Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
Industrial uses

1.3 Details of the supplier of the safety data sheet

Supplier

Bio-Circle Surface Technology AG

Street : Aahusweg 16

Postal code/City : 6403 Küssnacht am Rigi

Telephone : 0041 41 878 1166

Telefax : 0041 41 878 1347

Information contact : service@bio-circle.ch

1.4 Emergency telephone number

+41 (0)442515151

Schweizerisches Toxikologisches Informationszentrum, 145

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]

Aquatic Chronic 3 ; H412 - Hazardous to the aquatic environment : Chronic 3 ; Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard statements

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P273 Avoid release to the environment.

2.3 Other hazards

None

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Hazardous ingredients

ALANINE N,N-BIS(CARBOXYMETHYL), -TRINATRIUMSALT IN WATER ; REACH No. : 01-0000016977-53-XXXX ; CAS No. : 164462-16-2

Weight fraction : $\geq 5 - < 10$ %

Classification 1272/2008 [CLP] : Met. Corr. 1 ; H290

(Z)-N-METHYL-N-(1-OXO-9-OCTADECENYL)GLYCINE ; EC No. : 203-749-3 ; CAS No. : 110-25-8

Weight fraction : $\geq 0,5 - < 1$ %

Classification 1272/2008 [CLP] : Eye Dam. 1 ; H318 Acute Tox. 4 ; H332 Skin Irrit. 2 ; H315 Aquatic Acute 1 ; H400 Aquatic Chronic 1 ; H410

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Additional information

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information

When in doubt or if symptoms are observed, get medical advice. Never give anything by mouth to an unconscious person or a person with cramps.

Following inhalation

Remove casualty to fresh air and keep warm and at rest.

In case of skin contact

After contact with skin, wash immediately with plenty of water and soap. Rub greasy ointment into the skin.

After eye contact

Protect uninjured eye. In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

Following ingestion

Rinse mouth thoroughly with water. Let 1 glass of water be drunken in little sips (dilution effect). Do NOT induce vomiting. Call a physician immediately.

4.2 Most important symptoms and effects, both acute and delayed

No information available.

4.3 Indication of any immediate medical attention and special treatment needed

None

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water Foam Extinguishing powder Carbon dioxide (CO₂) Sand Nitrogen Extinguishing blanket

Unsuitable extinguishing media

Full water jet

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products

In case of fire may be liberated: Carbon monoxide , Carbon dioxide (CO₂) , Nitrogen oxides (NO_x)

5.3 Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

5.4 Additional information

The product itself does not burn. Move undamaged containers from immediate hazard area if it can be done safely. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Special danger of slipping by leaking/spilling product.

6.2 Environmental precautions

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

6.3 Methods and material for containment and cleaning up

Clear spills immediately. Wipe up with absorbent material (eg. cloth, fleece). Wash with plenty of water. Treat the recovered material as prescribed in the section on waste disposal.

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6.4 Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Keep container tightly closed.

7.2 Conditions for safe storage, including any incompatibilities

Keep/Store only in original container. Protect against : Frost .

7.3 Specific end use(s)

Observe technical data sheet. Observe instructions for use.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values

(Z)-N-METHYL-N-(1-OXO-9-OCTADECENYL)GLYCINE ; CAS No. : 110-25-8

Limit value type (country of origin) : STEL (CH)
Limit value : 0,2 mg/m³
Remark : 15 minutes average value
Version :

Limit value type (country of origin) : TWA (CH)
Parameter : E: inhalable fraction
Limit value : 0,1 mg/m³
Version :

DNEL-/PNEC-values

DNEL/DMEL

ALANINE N,N-BIS(CARBOXYMETHYL), -TRINATRIUMSALT IN WATER ; CAS No. : 164462-16-2

Limit value type : DNEL worker (local)
Exposure route : Inhalation
Exposure frequency : Short-term
Limit value : 40 mg/m³
Limit value type : DNEL worker (local)
Exposure route : Inhalation
Exposure frequency : Long-term
Limit value : 4 mg/m³
Limit value type : DNEL worker (systemic)
Exposure route : Inhalation
Exposure frequency : Short-term
Limit value : 40 mg/m³
Limit value type : DNEL worker (systemic)
Exposure route : Inhalation
Exposure frequency : Long-term
Limit value : 40 mg/m³

(Z)-N-METHYL-N-(1-OXO-9-OCTADECENYL)GLYCINE ; CAS No. : 110-25-8

Limit value type : DNEL Consumer (local)
Exposure route : Inhalation
Exposure frequency : Short-term
Limit value : 9 mg/m³
Limit value type : DNEL/DMEL (Consumer)
Exposure route : Oral

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Exposure frequency : Short-term
Limit value : 92 mg/kg bw/day
Limit value type : DNEL/DMEL (Consumer)
Exposure route : Oral
Exposure frequency : Long-term
Limit value : 5 mg/kg bw/day
Limit value type : DNEL Consumer (systemic)
Exposure route : Dermal
Exposure frequency : Short-term
Limit value : 50 mg/kg bw/day
Limit value type : DNEL Consumer (systemic)
Exposure route : Dermal
Exposure frequency : Long-term
Limit value : 5 mg/kg bw/day
Limit value type : DNEL Consumer (systemic)
Exposure route : Inhalation
Exposure frequency : Short-term
Limit value : 9 mg/m³
Limit value type : DNEL Consumer (systemic)
Exposure route : Inhalation
Exposure frequency : Long-term
Limit value : 0,1 mg/m³
Limit value type : DNEL worker (local)
Exposure route : Inhalation
Exposure frequency : Short-term
Limit value : 18 mg/m³
Limit value type : DNEL worker (local)
Exposure route : Inhalation
Exposure frequency : Long-term
Limit value : 0,01 mg/m³
Limit value type : DNEL worker (systemic)
Exposure route : Dermal
Exposure frequency : Short-term
Limit value : 100 mg/kg bw/day
Limit value type : DNEL worker (systemic)
Exposure route : Dermal
Exposure frequency : Long-term
Limit value : 10 mg/kg bw/day
Limit value type : DNEL worker (systemic)
Exposure route : Inhalation
Exposure frequency : Short-term
Limit value : 18 mg/m³
Limit value type : DNEL worker (systemic)
Exposure route : Inhalation
Exposure frequency : Long-term
Limit value : 0,2 mg/m³

PNEC

ALANINE N,N-BIS(CARBOXYMETHYL), -TRINATRIUMSALT IN WATER ; CAS No. : 164462-16-2

Limit value type : PNEC (Aquatic, freshwater)
Exposure route : Water (Including sewage plant)
Limit value : 2 mg/l
Limit value type : PNEC (Aquatic, marine water)
Exposure route : Water (Including sewage plant)
Limit value : 0,2 mg/l
Limit value type : PNEC (Sediment, freshwater)
Limit value : 24 mg/kg

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Limit value type : PNEC Soil, Freshwater
Exposure route : Soil
Limit value : 2,5 mg/kg
Limit value type : PNEC (Sewage treatment plant)
Exposure route : Water (Including sewage plant)
Limit value : 100 mg/l
(Z)-N-METHYL-N-(1-OXO-9-OCTADECENYL)GLYCINE ; CAS No. : 110-25-8
Limit value type : PNEC (Aquatic, freshwater)
Exposure route : Water (Including sewage plant)
Limit value : 0,43 µg/l
Limit value type : PNEC (Aquatic, intermittent release)
Exposure route : Water (Including sewage plant)
Limit value : 4,3 µg/l
Limit value type : PNEC (Aquatic, marine water)
Exposure route : Water (Including sewage plant)
Limit value : 0,043 µg/l
Limit value type : PNEC (Sewage treatment plant)
Exposure route : Water (Including sewage plant)
Limit value : 13 mg/l

8.2 Exposure controls

Personal protection equipment

Eye/face protection



Wear suitable safety goggles in case of splash.

Suitable eye protection

EN 166.

Skin protection

Hand protection



Suitable gloves type : EN 374.

Suitable material : NBR (Nitrile rubber)

Breakthrough time : 480 min.

Thickness of the glove material : 0.4 mm

Remark : The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

General information

Do not put any product-impregnated cleaning rags into your trouser pockets. When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes. P362+P364 - Take off contaminated clothing and wash it before reuse. P264 - Wash hands thoroughly after handling.

8.3 Additional information

No tests have been performed. Selection made for preparations according to the best available knowledge and information on ingredients. In the case of preparations the resistance of glove materials cannot be calculated in advance so it has to be tested before use.

SECTION 9: Physical and chemical properties

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9.1 Information on basic physical and chemical properties

Appearance

Physical state : viscous

Colour : colourless

Odour

odourless

Safety characteristics

Freezing point :	(1013 hPa)	<=	0	°C	
Initial boiling point and boiling range :	(1013 hPa)	<	100	°C	
Flash point :			none		DIN EN ISO 13736
Auto-ignition temperature :			none		
Flammability :			non-flammable		
Upper explosion limit :	(D-LIMONENE)		6,1	Vol-%	Literature value
Vapour pressure :	(20 °C)	<	24	hPa	Calculated
Density :	(20 °C)	approx.	1,04	g/cm ³	
Water solubility :	(20 °C)		completely miscible		
pH :	(20 °C)	approx.	11		
Cinematic viscosity :	(20 °C)	approx.	140	mm ² /s	
Relative vapour density :	(20 °C)		not determined		
Maximum VOC content (EC) :			0	Weight-%	
Maximum VOC content (Switzerland) :			0	Weight-%	
Taxable VOC content (Switzerland) :			0	Weight-%	

9.2 Other information

No further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity

This material is considered to be non-reactive under normal use conditions.

10.2 Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

No information available.

10.5 Incompatible materials

No information available.

10.6 Hazardous decomposition products

No known hazardous decomposition products.
Decomposition products in case of fire: see section 5.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Acute oral toxicity

Parameter : LD50 (ALANINE N,N-BIS(CARBOXYMETHYL), -TRINATRIUMSALT IN WATER ; CAS No. : 164462-16-2)
Exposure route : Oral
Species : Rat

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Effective dose : > 4000 mg/kg
Parameter : LD50 ((Z)-N-METHYL-N-(1-OXO-9-OCTADECENYL)GLYCINE ; CAS No. : 110-25-8)
Exposure route : Oral
Species : Rat
Effective dose : 9,2 g/kg
Method : OECD 403

Acute dermal toxicity

Parameter : LD50 (ALANINE N,N-BIS(CARBOXYMETHYL), -TRINATRIUMSALT IN WATER ; CAS No. : 164462-16-2)
Exposure route : Dermal
Species : Rat
Effective dose : > 4000 mg/kg
Method : OECD 402

Acute inhalation toxicity

Parameter : LC50 (ALANINE N,N-BIS(CARBOXYMETHYL), -TRINATRIUMSALT IN WATER ; CAS No. : 164462-16-2)
Exposure route : Inhalation
Species : Rat
Effective dose : > 5 mg/l
Parameter : LC50 ((Z)-N-METHYL-N-(1-OXO-9-OCTADECENYL)GLYCINE ; CAS No. : 110-25-8)
Exposure route : Inhalation
Species : Rat
Effective dose : 1,85 mg/l
Exposure time : 4 h

Corrosion

Skin corrosion/irritation

No further relevant information available.

Serious eye damage/eye irritation

No further relevant information available.

Respiratory or skin sensitisation

Skin sensitisation

No further relevant information available.

Sensitisation to the respiratory tract

No further relevant information available.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity

No further relevant information available.

Germ cell mutagenicity

No further relevant information available.

Reproductive toxicity

No further relevant information available.

STOT-single exposure

No further relevant information available.

STOT-repeated exposure

No further relevant information available.

Aspiration hazard

No further relevant information available.

11.2 Information on other hazards

Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

Toxicokinetics, metabolism and distribution

There are no data available on the preparation/mixture itself.

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Additional information

Preparation not tested. The statement is derived from the properties of the single components.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity

Acute (short-term) fish toxicity

Parameter : LC50 (ALANINE N,N-BIS(CARBOXYMETHYL), -TRINATRIUMSALT IN WATER ; CAS No. : 164462-16-2)
Species : Danio rerio (zebrafish)
Evaluation parameter : Acute (short-term) fish toxicity
Effective dose : > 110 mg/l
Exposure time : 96 h
Method : Regulation (EC) No. 440/2008, Annex C.1
Parameter : LC50 ((Z)-N-METHYL-N-(1-OXO-9-OCTADECENYL)GLYCINE ; CAS No. : 110-25-8)
Species : Acute (short-term) fish toxicity
Effective dose : 3,2 - 4,6 mg/l
Exposure time : 96 h

Chronic (long-term) fish toxicity

Parameter : NOEC (ALANINE N,N-BIS(CARBOXYMETHYL), -TRINATRIUMSALT IN WATER ; CAS No. : 164462-16-2)
Species : Oncorhynchus mykiss (Rainbow trout)
Evaluation parameter : Chronic (long-term) fish toxicity
Effective dose : = 100 mg/l
Exposure time : 28 D
Method : OECD 204

Acute (short-term) toxicity to crustacea

Parameter : EC50 (ALANINE N,N-BIS(CARBOXYMETHYL), -TRINATRIUMSALT IN WATER ; CAS No. : 164462-16-2)
Species : Daphnia magna (Big water flea)
Evaluation parameter : Acute (short-term) toxicity to crustacea
Effective dose : > 100 mg/l
Exposure time : 48 h
Method : Regulation (EC) No. 440/2008, Annex C.2
Parameter : EC50 ((Z)-N-METHYL-N-(1-OXO-9-OCTADECENYL)GLYCINE ; CAS No. : 110-25-8)
Species : Daphnia magna (Big water flea)
Evaluation parameter : Acute (short-term) daphnia toxicity
Effective dose : 0,53 mg/l
Exposure time : 48 h
Evaluation : Very toxic to daphnia.

Chronic (long-term) toxicity to aquatic invertebrate

Parameter : NOEC (ALANINE N,N-BIS(CARBOXYMETHYL), -TRINATRIUMSALT IN WATER ; CAS No. : 164462-16-2)
Species : Daphnia magna (Big water flea)
Evaluation parameter : Chronic (long-term) toxicity to aquatic invertebrate
Effective dose : >= 100 mg/l
Exposure time : 21 D
Method : Regulation (EC) No. 440/2008, Annex C.20

Acute (short-term) toxicity to algae and cyanobacteria

Parameter : EC50 (ALANINE N,N-BIS(CARBOXYMETHYL), -TRINATRIUMSALT IN WATER ; CAS No. : 164462-16-2)
Species : Scenedesmus subspicatus
Evaluation parameter : Acute (short-term) toxicity to algae and cyanobacteria
Effective dose : > 200 mg/l

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Exposure time : 72 h
Parameter : ErC50 ((Z)-N-METHYL-N-(1-OXO-9-OCTADECENYL)GLYCINE ; CAS No. : 110-25-8)
Species : Acute (short-term) algae toxicity
Effective dose : 5,1 mg/l
Exposure time : 72 h

Sewage treatment plant

Parameter : EC20 ((Z)-N-METHYL-N-(1-OXO-9-OCTADECENYL)GLYCINE ; CAS No. : 110-25-8)
Inoculum : Activated sludge
Effective dose : 50 mg/l
Exposure time : 1 h

12.2 Persistence and degradability

Biodegradation

Parameter : BOD (% of ThOD) (ALANINE N,N-BIS(CARBOXYMETHYL), -TRINATRIUMSALT IN WATER ; CAS No. : 164462-16-2)
Inoculum : Degree of elimination
Evaluation parameter : Aerobic
Degradation rate : > 80 - 90 %
Test duration : 28 D
Evaluation : Readily biodegradable (according to OECD criteria).
Method : OECD 301F
Parameter : DOC reduction (ALANINE N,N-BIS(CARBOXYMETHYL), -TRINATRIUMSALT IN WATER ; CAS No. : 164462-16-2)
Inoculum : Degree of elimination
Evaluation parameter : Aerobic
Degradation rate : > 90 - 100 %
Test duration : 28 D
Method : OECD 301F
Parameter : Biodegradation ((Z)-N-METHYL-N-(1-OXO-9-OCTADECENYL)GLYCINE ; CAS No. : 110-25-8)
Evaluation : Not readily biodegradable (according to OECD criteria)

12.3 Bioaccumulative potential

Parameter : Partition coefficient n-octanol /water (log P O/W) ((Z)-N-METHYL-N-(1-OXO-9-OCTADECENYL)GLYCINE ; CAS No. : 110-25-8)
Value : 6,83
No indication of bioaccumulation potential.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6 Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7 Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Ordinance on the avoidance and disposal of waste (ADWO) SR 814.600.

Before intended use

Waste code according to the lists for the movement of waste

07 06 01S (Aqueous washing liquids and mother liquors)

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20 01 29* (Detergents containing hazardous substances) 20 01 29S (Detergents containing hazardous substances)

Other disposal recommendations

Dispose of waste according to applicable legislation. Dispose of contents/container to an appropriate recycling or disposal facility. Contaminated packages must be completely emptied and can be re-used following proper cleaning. Handle contaminated packages in the same way as the substance itself.

13.2 Additional information

The allocation of waste identity numbers/waste descriptions must be carried out according to the VVEA, specific to the industry and process.

SECTION 14: Transport information

14.1 UN number

No dangerous good in sense of these transport regulations.

14.2 UN proper shipping name

No dangerous good in sense of these transport regulations.

14.3 Transport hazard class(es)

No dangerous good in sense of these transport regulations.

14.4 Packing group

No dangerous good in sense of these transport regulations.

14.5 Environmental hazards

No dangerous good in sense of these transport regulations.

14.6 Special precautions for user

None

14.7 Maritime transport in bulk according to IMO instruments

No transport as bulk according to IBC Code.

SECTION 15: Regulatory information

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

EU legislation

Authorisations and/or restrictions on use

Restrictions on use

Use restriction according to REACH annex XVII, no. : 3, 75

National regulations

Other regulations, restrictions and prohibition regulations

Switzerland

Chemicals Ordinance, ChemO (SR 813.11)

Chemical Risk Reduction Ordinance, ORRChem (SR 814.81)

15.2 Chemical Safety Assessment

For this substance a chemical safety assessment has not been carried out.

SECTION 16: Other information

16.1 Indication of changes

09. Information on basic physical and chemical properties

16.2 Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route (Europäisches Übereinkommen über die Beförderung gefährlicher Güter auf der Straße)

AOX: adsorbierbare organisch gebundene Halogene

AwSV: Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen

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CAS: Chemical Abstracts Service (Unterabteilung der American Chemical Society)
CLP: Verordnung (EG) Nr. 1272/2008 über die Einstufung, Kennzeichnung und Verpackung von Stoffen und Gemischen (Classification Labelling and Packaging)
EAK / AVV: europäischer Abfallartenkatalog / Abfallverzeichnis-Verordnung
ECHA: Europäische Chemikalienagentur (European Chemicals Agency)
EINECS: : Altstoffverzeichnis (European Inventory of Existing Commercial Chemical Substances)
GHS: Global harmonisiertes System zur Einstufung und Kennzeichnung von Chemikalien (Globally Harmonized System of Classification and Labelling of Chemicals)
IATA: Internationale Luftverkehrs-Vereinigung (International Air Transport Association)
ICAO: Internationale Zivilluftfahrtorganisation (International Civil Aviation Organization)
IMDG: Gefahrgutkennzeichnung für gefährliche Güter im Seeschiffverkehr (International Maritime Code for Dangerous Goods)
RID: Regelung zur internationalen Beförderung gefährlicher Güter im Schienenverkehr (Règlement concernant le transport international ferroviaire de marchandises dangereuses)
TRGS: Technische Regel für den Umgang mit Gefahrstoffen
VbF: Verordnung über brennbare Flüssigkeiten
VOC: flüchtige organische Verbindung (volatile organic compound)
VVEA: Verordnung über die Vermeidung und die Entsorgung von Abfällen
VwVwS: Verwaltungsvorschrift wassergefährdender Stoffe
WGK: Wassergefährdungsklasse

16.3 Key literature references and sources for data

DGUV: GESTIS-Stoffdatenbank
ECHA: Classification And Labelling Inventory
ECHA: Pre-registered Substances
ECHA: Registered Substances
EC_Safety Data Sheet of Suppliers
ESIS: European Chemical Substances Information System
GDL: Gefahrstoffdatenbank der Länder
UBA Rigoletto: Wassergefährdende Stoffe
Regulation (EC) No. 1907/2006 of the European Parliament and of the Council
Regulation (EC) No. 1272/2008 of the European Parliament and of the Council

16.4 Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].
Evaluation :
Aquatic Chronic 3 : Calculation method.

16.5 Relevant H- and EUH-phrases (Number and full text)

H290	May be corrosive to metals.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H332	Harmful if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

16.6 Training advice

None

16.7 Additional information

None

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.