

Safety Data Sheet

according to UK REACH Regulation

implantlink® semi forte (Base + Catalyst)

Revision date: 05.05.2022

Product code: 10035.1

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

1.1. Product identifier

implantlink® semi forte (Base + Catalyst)

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

Use of the substance/mixture

Provisional cement for use in dentistry.

1.3. Details of the supplier of the safety data sheet

Company name:	DETAX GmbH	
Street:	Carl-Zeiss-Straße 4	
Place:	D-76275 Ettlingen	
Telephone:	+49 7243/510-0	Telefax: +49 7243/510-100
e-mail:	post@detax.com	
Internet:	www.detax.com	
Responsible Department:	This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 a.m. - 4.00 p.m.)	

1.4. Emergency telephone number:

+1-800-424-9300 (CHEMTREC worldwide)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

Skin Sens. 1; H317
Aquatic Chronic 2; H411

Full text of hazard statements: see SECTION 16.

2.2. Label elements

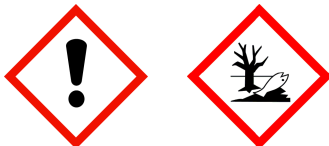
GB CLP Regulation

Hazard components for labelling

aliphatic urethane acrylate
2-hydroxyethyl methacrylate
1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with oxirane, 4-(dimethylamino)benzoate
phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide

Signal word: Warning

Pictograms:



Hazard statements

H317 May cause an allergic skin reaction.
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P302+P352 IF ON SKIN: Wash with plenty of water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.

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P391 Collect spillage.
 P501 Dispose of contents/ container in accordance with local and national regulations.

Additional advice on labelling

According to Regulation (EC) 1272/2008, art.1 No. 5 (d) this product as a medical product must not be labelled!

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Mixture of methacrylic resins with auxiliary matters.

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
2143103-44-8	aliphatic urethane acrylate			40 - < 45 %
	944-336-4		01-2120266262-60	
	Skin Sens. 1B, Aquatic Chronic 3; H317 H412			
6606-59-3	1,6-hexanediol dimethacrylate			1 - < 5 %
	229-551-7			
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335			
72846-00-5	1-benzyl-5-phenyl-hexahydropyrimidine-2,4,-6-trione			1 - < 5 %
			01-2120226211-75	
	Acute Tox. 4; H302			
868-77-9	2-hydroxyethyl methacrylate			< 1 %
	212-782-2	607-124-00-X	01-2119490169-29	
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1; H315 H319 H317			
3380-34-5	2,4,4'-trichloro-2'-hydroxy-diphenyl-ether, 5-chloro-2-(2,4-dichlorophenoxy)phenol, triclosan			< 1 %
	222-182-2	604-070-00-9		
	Skin Irrit. 2, Eye Irrit. 2, Aquatic Acute 1, Aquatic Chronic 1; H315 H319 H400 H410			
2067275-86-7	1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with oxirane, 4-(dimethylamino)benzoate			< 1 %
	Skin Sens. 1B, Aquatic Chronic 4; H317 H413			
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide			< 0.1 %
	423-340-5	015-189-00-5	01-2119489401-38	
	Skin Sens. 1A, Aquatic Chronic 4; H317 H413			

Full text of H and EUH statements: see section 16.

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Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
2143103-44-8	944-336-4	aliphatic urethane acrylate	40 - < 45 %
		oral: LD50 = >5000 mg/kg	
72846-00-5		1-benzyl-5-phenyl-hexahydropyrimidine-2,4,-6-trione	1 - < 5 %
		oral: ATE = 500 mg/kg	
868-77-9	212-782-2	2-hydroxyethyl methacrylate	< 1 %
		dermal: LD50 = >5000 mg/kg; oral: LD50 = 5564 mg/kg	
3380-34-5	222-182-2	2,4,4'-trichloro-2'-hydroxy-diphenyl-ether, 5-chloro-2-(2,4-dichlorophenoxy)phenol, triclosan	< 1 %
		dermal: LD50 = >6000 mg/kg; oral: LD50 = >5000 mg/kg M acute; H400: M=100 M chron.; H410: M=100	
162881-26-7	423-340-5	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	< 0.1 %
		dermal: LD50 = >2000 mg/kg; oral: LD50 = >2000 mg/kg	

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

After ingestion

Rinse mouth immediately and drink plenty of water.

Seek immediately medical advice. Do not induce vomiting. In case of spontaneous vomiting take care of an unhindered flow out of the vomit (danger of suffocation).

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Suppress gases/vapours/mists with water spray jet. 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

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General advice

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For cleaning up

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

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

Advice on safe handling

No special measures are necessary.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.

Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink, smoke, sniff.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed.

Hints on joint storage

Keep away from spontaneous flammable or combustible substances.

Further information on storage conditions

Keep only in the original container in a cool, dry and well-ventilated place, away from foodstuffs. Keep away from all kind of lighth.

7.3. Specific end use(s)

Luting cement for implant retained dental restorations.

For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. 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.

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Suitable are gloves of the following material: Butyl caoutchouc (butyl rubber)

Skin protection

Use of protective clothing. Wear suitable protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Paste , low-viscosity
 Colour: base: white-opaque, catalyst: semi-transparent
 Odour: aromatic

Test method

Changes in the physical state

Melting point/freezing point: not determined
 Boiling point or initial boiling point and boiling range: not determined
 Flash point: >100 °C DIN 51755

Flammability

Solid/liquid: not applicable
 Gas: not applicable

Explosive properties

The product is not: Explosive.

Lower explosion limits: not determined
 Upper explosion limits: not determined
 Auto-ignition temperature: not determined
 Decomposition temperature: not determined
 pH-Value: not determined
 Viscosity / dynamic: (at 23 °C) 40000 mPa·s Rheostress
 Water solubility: The study does not need to be conducted because the substance is known to be insoluble in water.

Solubility in other solvents

not determined

Partition coefficient n-octanol/water: not determined
 Vapour pressure: (at 20 °C) <1 hPa
 Density (at 20 °C): 1,1 g/cm³ DIN 51757
 Relative vapour density: not determined

9.2. Other information

Information with regard to physical hazard classes

Sustaining combustion: Not sustaining combustion

Oxidizing properties

The product is not: oxidising.

Other safety characteristics

Solid content: not determined

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Evaporation rate: not determined

Further Information

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Reacts with :
oxidising agents, radicals forming substances or heavy metal ions.

10.4. Conditions to avoid

Ultra-violet light and daylight initiate polymerisation of the product. Therefore keep only in tightly closed containers away from any sources of light. Keep at temperature not exceeding 25°C/ 77°F.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

In case of fire, acrid acrylic fumes may occur.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in GB CLP Regulation

Acute toxicity

Based on available data, the classification criteria are not met.

For the product itself no toxicological data are available. In products with a comparable composition, a LD50 (orally, species rat) of > 5000 mg/kg has been found.

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
2143103-44-8	aliphatic urethane acrylate				
	oral	LD50 >5000 mg/kg	Ratte	Lieferanten-Sicherheit sdatenblatt	OECD 401
72846-00-5	1-benzyl-5-phenyl-hexahydropyrimidine-2,4,-6-trione				
	oral	ATE 500 mg/kg			
868-77-9	2-hydroxyethyl methacrylate				
	oral	LD50 5564 mg/kg	Rat		
	dermal	LD50 >5000 mg/kg	Rabbit		
3380-34-5	2,4,4'-trichloro-2'-hydroxy-diphenyl-ether, 5-chloro-2-(2,4-dichlorophenoxy)phenol, triclosan				
	oral	LD50 >5000 mg/kg	Rat	OECD 401	
	dermal	LD50 >6000 mg/kg	Rat	OECD 402	
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide				
	oral	LD50 >2000 mg/kg	Rat	OECD 401	
	dermal	LD50 >2000 mg/kg	Rat	OECD 402	

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

May cause an allergic skin reaction. (aliphatic urethane acrylate; 2-hydroxyethyl methacrylate; 1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with oxirane, 4-(dimethylamino)benzoate; phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide)

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Further information

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

Toxic to aquatic life with long lasting effects.

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
2143103-44-8	aliphatic urethane acrylate					
	Acute fish toxicity	LC50 18 mg/l	96 h	Oncorhynchus mykiss	Lieferanten-SDB	OECD 203
	Acute crustacea toxicity	EC50 15.9 mg/l	48 h	Daphnia magna	Lieferanten-SDB	OECD 202
	Acute bacteria toxicity	(EC50 25.4 mg/l)		Pseudokirchneriella subcapitata	Lieferanten-SDB	OECD 201
868-77-9	2-hydroxyethyl methacrylate					
	Acute fish toxicity	LC50 >100 mg/l	96 h	Oryzias latipes		OECD 203
	Acute algae toxicity	ErC50 836 mg/l	72 h	Selenastrum capricornutum		OECD 201
	Acute crustacea toxicity	EC50 380 mg/l	48 h	Daphnia magna		OECD 202
3380-34-5	2,4,4'-trichloro-2'-hydroxy-diphenyl-ether, 5-chloro-2-(2,4-dichlorophenoxy)phenol, triclosan					
	Acute fish toxicity	LC50 0,54 mg/l	96 h	Danio rerio (zebrafish)	OECD 203	
	Acute algae toxicity	ErC50 0,00161 mg/l	72 h	Desmodesmus subspicatus		
	Acute crustacea toxicity	EC50 0,427 mg/l	48 h	Daphnia magna (Big water flea)	OECD 202	
	Fish toxicity	NOEC 0,0341 mg/l	96 d	Oncorhynchus mykiss (Rainbow trout)	OPP 72-4	
	Crustacea toxicity	NOEC 0,04 mg/l	21 d	Daphnia magna (Big water flea)	OECD 211	
	Acute bacteria toxicity	(EC50 11 mg/l)	3 h	Activated sludge	OECD 209	
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide					
	Acute fish toxicity	LC50 >0,09 mg/l	96 h	Danio rerio (zebrafish)	OECD 203	
	Acute algae toxicity	ErC50 >0,26 mg/l	72 h	Desmodesmus subspicatus	OECD 201	
	Acute crustacea toxicity	EC50 >1,175 mg/l	48 h	Daphnia magna (Big water flea)	OECD 202	
	Crustacea toxicity	NOEC >0,008 mg/l	21 d	Daphnia magna (Big water flea)	OECD 211	
	Acute bacteria toxicity	(EC50 >100 mg/l)	3 h	OECD 209		

12.2. Persistence and degradability

The product has not been tested.

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CAS No	Chemical name	Method	Value	d	Source
		Evaluation			
868-77-9	2-hydroxyethyl methacrylate		92-100%	14	
	Readily biodegradable (according to OECD criteria).				
3380-34-5	2,4,4'-trichloro-2'-hydroxy-diphenyl-ether, 5-chloro-2-(2,4-dichlorophenoxy)phenol, triclosan				
	BOD (% of ThOD).	37%		28	OECD 301B/ ISO 9439/ EEC 92/69/V, C.4-C
	Not readily biodegradable (according to OECD criteria)				
	specific analysis.	99,4%		14	OECD 302B/ ISO 9888/ EEC 92/69/V, C.9
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide				
	CO2 formation (% of the theoretical value).	1%		29	
	Not readily biodegradable (according to OECD criteria)				

12.3. Bioaccumulative potential

The product has not been tested.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
72846-00-5	1-benzyl-5-phenyl-hexahydropyrimidine-2,4,-6-trione	2,3
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	5,8

BCF

CAS No	Chemical name	BCF	Species	Source
3380-34-5	2,4,4'-trichloro-2'-hydroxy-diphenyl-ether, 5-chloro-2-(2,4-dichlorophenoxy)phenol, triclosan	4.157	Danio rerio (zebrafish)	OECD 305
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	<5	Cyprinus carpio (Common Carp)	OECD 305

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

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

Not identified as PBT/ vPvB substances

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.

Further information

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

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the

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substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:	UN 3082
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9
Classification code:	M6
Special Provisions:	274 335 375 601
Limited quantity:	5 L
Excepted quantity:	E1
Transport category:	3
Hazard No:	90
Tunnel restriction code:	-

Other applicable information (land transport)

Contains: Triclosan

Inland waterways transport (ADN)

14.1. UN number or ID number:	UN 3082
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9
Classification code:	M6
Special Provisions:	274 335 375 601
Limited quantity:	5 L
Excepted quantity:	E1

Marine transport (IMDG)

14.1. UN number or ID number:	UN 3082
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9
Special Provisions:	274, 335, 969
Limited quantity:	5 L
Excepted quantity:	E1
EmS:	F-A, S-F

Other applicable information (marine transport)

Contains Triclosan
Flash point: > 100°C

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:	UN 3082
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9
Special Provisions:	A97 A158 A197 A215
Limited quantity Passenger:	30 kg G
Passenger LQ:	Y964
Excepted quantity:	E1
IATA-packing instructions - Passenger:	964
IATA-max. quantity - Passenger:	450 L

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IATA-packing instructions - Cargo: 964
 IATA-max. quantity - Cargo: 450 L

Other applicable information (air transport)

Contains Triclosan

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: Yes

14.6. Special precautions for user

No information available.

14.7. Maritime transport in bulk according to IMO instruments

not applicable

SECTION 15: Regulatory information

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

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 75

Information according to 2012/18/EU (SEVESO III): E2 Hazardous to the Aquatic Environment

Additional information

To follow: 850/2004/EC, 79/117/EEC, 689/2008/EC

National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

Water hazard class (D): 3 - highly hazardous to water

Skin resorption/Sensitization: Causes allergic hypersensitivity reactions.

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

CLP: Classification, labelling and Packaging

REACH: Registration, Evaluation and Authorization of Chemicals

GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals

UN: United Nations

DNEL: Derived No Effect Level

DMEL: Derived Minimal Effect Level

PNEC: Predicted No Effect Concentration

ATE: Acute toxicity estimate

LL50: Lethal loading, 50%

EL50: Effect loading, 50%

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EC50: Effective Concentration 50%
 ErC50: Effective Concentration 50%, growth rate
 NOEC: No Observed Effect Concentration
 BCF: Bio-concentration factor
 PBT: persistent, bioaccumulative, toxic
 vPvB: very persistent, very bioaccumulative
 RID: Regulations concerning the international carriage of dangerous goods by rail
 EmS: Emergency Schedules
 MFAG: Medical First Aid Guide
 ICAO: International Civil Aviation Organization
 MARPOL: International Convention for the Prevention of Marine Pollution from Ships
 IBC: Intermediate Bulk Container
 VOC: Volatile Organic Compounds
 SVHC: Substance of Very High Concern
 ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
 (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation
 intérieures)
 For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety
 assessment, chapter R.20 (Table of terms and abbreviations).

Classification for mixtures and used evaluation method according to GB CLP Regulation

Classification	Classification procedure
Skin Sens. 1; H317	Calculation method
Aquatic Chronic 2; H411	Calculation method

Relevant H and EUH statements (number and full text)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
H413	May cause long lasting harmful effects to aquatic life.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)