

according to Regulation (EC) No 1907/2006

### medicalprint® mould 2.0

Revision date: 23.10.2019

Product code: 1093

Page 1 of 12

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

### 1.1. Product identifier

medicalprint® mould 2.0

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

#### Use of the substance/mixture

Ligth curing one component material for the fabrication of earmoulds.

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

Company name:	DETAX GmbH & Co. KG	
Street:	Carl-Zeiss-Strasse	
Place:	D-76275 Ettlingen	
Telephone:	+49 7243/510-0	Telefax: +49 7243/510-100
e-mail:	post@detax.de	
Internet:	www.detax.de	
Responsible Department:	Emergency number:	

+49 7243/510-0  
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:

+49 7243/510-0  
This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 - 4.00 p.m.)

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### Regulation (EC) No. 1272/2008

Hazard categories:

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2

Respiratory or skin sensitisation: Skin Sens. 1A

Specific target organ toxicity - single exposure: STOT SE 3

Hazardous to the aquatic environment: Aquatic Chronic 2

Hazard Statements:

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

Toxic to aquatic life with long lasting effects.

### 2.2. Label elements

#### Regulation (EC) No. 1272/2008

#### Hazard components for labelling

isopropylidenediphenol peg-2 dimethacrylate

Urethane Dimethacrylate

2-Propenoic acid, (5-ethyl-1,3-dioxan-5-yl)methyl ester

Tricyclodecane dimethanol diacrylate

diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

2-hydroxyethyl methacrylate

2,2-bis(acryloyloxymethyl)butyl acrylate, trimethylolpropane triacrylate

**Signal word:** Warning

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

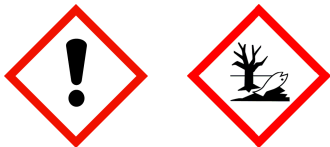
### medicalprint® mould 2.0

Revision date: 23.10.2019

Product code: 1093

Page 2 of 12

#### Pictograms:



#### Hazard statements

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
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.
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.
P391	Collect spillage.
P501	Dispose of contents/ container in accordance with local and national regulations.

#### 2.3. Other hazards

No information available.

### SECTION 3: Composition/information on ingredients

#### 3.2. Mixtures

##### Chemical characterization

Mixture of acrylic/ methacrylic resins with auxilliary matters.

according to Regulation (EC) No 1907/2006

### medicalprint® mould 2.0

Revision date: 23.10.2019

Product code: 1093

Page 3 of 12

#### Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
41637-38-1	isopropylidenediphenol peg-2 dimethacrylate			40 - < 45 %
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1A, STOT SE 3; H315 H319 H317 H335			
72869-86-4	Urethane Dimethacrylate			15 - < 20 %
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335			
66492-51-1	2-Propenoic acid, (5-ethyl-1,3-dioxan-5-yl)methyl ester			15 - < 20 %
	266-380-7			
	Skin Irrit. 2, Skin Sens. 1, Aquatic Chronic 2; H315 H317 H411			
42594-17-2	Tricyclodecane dimethanol diacrylate			10 - < 15 %
	255-901-3		01-2120051112-76	
	Skin Sens. 1B, Aquatic Chronic 2; H317 H411			
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide			1 - < 5 %
	278-355-8	015-203-00-X		
	Repr. 2, Skin Sens. 1B, Aquatic Chronic 2; H361f H317 H411			
868-77-9	2-hydroxyethyl methacrylate			< 1 %
	212-782-2	607-124-00-X		
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1; H315 H319 H317			
15625-89-5	2,2-bis(acryloyloxymethyl)butyl acrylate, trimethylolpropane triacrylate			< 1 %
	239-701-3	607-111-00-9		
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, Aquatic Acute 1, Aquatic Chronic 1; H315 H319 H317 H400 H410			

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

## 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

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

#### 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

according to Regulation (EC) No 1907/2006

### medicalprint® mould 2.0

Revision date: 23.10.2019

Product code: 1093

Page 4 of 12

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

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

Absorb with liquid-binding material (e.g. 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

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

#### Advice on protection against fire and explosion

No special fire protection measures are necessary.

### 7.2. Conditions for safe storage, including any incompatibilities

#### Requirements for storage rooms and vessels

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations.

#### 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 dry and well-ventilated place, away from foodstuffs. Keep away from all kind of ligh. An inert gas blanket should not be applied, because the stability of the product depends on the presence of oxygen (air).

### 7.3. Specific end use(s)

Ligh curing one component material for the fabrication of earmoulds.

according to Regulation (EC) No 1907/2006

### medicalprint® mould 2.0

Revision date: 23.10.2019

Product code: 1093

Page 5 of 12

For use by trained specialist staff.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

### 8.2. Exposure controls

#### Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

#### Protective and hygiene measures

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.

#### Eye/face protection

Suitable eye protection: goggles.

#### 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.

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

#### Skin protection

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:	liquid:
Colour:	several shades, according to the product name
Odour:	faintly like esters

#### Test method

pH-Value:	not determined
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#### Changes in the physical state

Melting point:	not determined
Initial boiling point and boiling range:	not determined

Flash point:	>100 °C DIN 51755
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#### Flammability

Solid:	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

Solid:	not applicable
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according to Regulation (EC) No 1907/2006

### medicalprint® mould 2.0

Revision date: 23.10.2019

Product code: 1093

Page 6 of 12

Gas: not applicable

Decomposition temperature:  $\geq 190$  °C

#### **Oxidizing properties**

Not oxidizing.

Vapour pressure: <1 hPa  
(at 20 °C)

Density (at 20 °C): 1,09 g/cm<sup>3</sup> DIN 51757

Water solubility: insoluble

#### **Solubility in other solvents**

not determined

Partition coefficient: not determined

Vapour density: not determined

Evaporation rate: not determined

#### **9.2. Other information**

Solid content: not determined

### 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 : strong oxidising agents, strong alkaline or acidic materials.

#### **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 at 15°C - 28°C / 59°F - 82 °F.

#### **10.5. Incompatible materials**

No information available.

#### **10.6. Hazardous decomposition products**

No known hazardous decomposition products.

### SECTION 11: Toxicological information

#### **11.1. Information on toxicological effects**

##### **Acute toxicity**

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

according to Regulation (EC) No 1907/2006

### medicalprint® mould 2.0

Revision date: 23.10.2019

Product code: 1093

Page 7 of 12

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
66492-51-1	2-Propenoic acid, (5-ethyl-1,3-dioxan-5-yl)methyl ester				
	oral	LD50 >2000 mg/kg	Rat		
	dermal	LD50 2000 mg/kg	Rat		
42594-17-2	Tricyclodecane dimethanol diacrylate				
	oral	LD50 >2000 mg/kg	Rat	OECD 423	
	dermal	LD50 >2000 mg/kg	Rat	OECD 402	
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide				
	oral	LD50 >5000 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rat		
868-77-9	2-hydroxyethyl methacrylate				
	oral	LD50 5050 mg/kg	Rat		
	dermal	LD50 >3000 mg/kg	Rabbit		
15625-89-5	2,2-bis(acryloyloxymethyl)butyl acrylate, trimethylolpropane triacrylate				
	oral	LD50 >5000 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rat		

#### Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

#### Sensitising effects

May cause an allergic skin reaction. (isopropylidenediphenol peg-2 dimethacrylate; Urethane Dimethacrylate; 2-Propenoic acid, (5-ethyl-1,3-dioxan-5-yl)methyl ester; Tricyclodecane dimethanol diacrylate; diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide; 2-hydroxyethyl methacrylate; 2,2-bis(acryloyloxymethyl)butyl acrylate, trimethylolpropane triacrylate)

#### Carcinogenic/mutagenic/toxic effects for reproduction

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

#### STOT-single exposure

May cause respiratory irritation. (isopropylidenediphenol peg-2 dimethacrylate)

#### 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.

#### Additional information on tests

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

### SECTION 12: Ecological information

#### 12.1. Toxicity

according to Regulation (EC) No 1907/2006

### medicalprint® mould 2.0

Revision date: 23.10.2019

Product code: 1093

Page 8 of 12

Toxic to aquatic life with long lasting effects.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method
66492-51-1	2-Propenoic acid, (5-ethyl-1,3-dioxan-5-yl)methyl ester					
	Acute fish toxicity	LC50 4 mg/l	96 h	Oncorhynchus mykiss (Rainbow trout)		
	Acute algae toxicity	ErC50 34 mg/l	72 h	Desmodesmus subspicatus.		
	Acute crustacea toxicity	EC50 20 mg/l	48 h	Daphnia magna (Big water flea)		
	Acute bacteria toxicity	(>1,000 mg/l)	3 h	Activated sludge		
42594-17-2	Tricyclodecane dimethanol diacrylate					
	Acute fish toxicity	LC50 1,65 mg/l	96 h	Brachydanio rerio (zebra-fish)	OECD 203	
	Acute algae toxicity	ErC50 1,6 mg/l	72 h	Pseudokirchneriella subcapitata	OECD 201	
	Acute crustacea toxicity	EC50 2,36 mg/l	48 h	Daphnia magna (Big water flea)	OECD 202	
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide					
	Acute algae toxicity	ErC50 >2,01 mg/l	72 h	Scenedesmus subspicatus		
	Acute crustacea toxicity	EC50 3,53 mg/l	48 h	Daphnia magna (Big water flea)		
	Acute bacteria toxicity	(>1000 mg/l)	3 h	Activated sludge		
868-77-9	2-hydroxyethyl methacrylate					
	Acute fish toxicity	LC50 227 mg/l	96 h	Pimephales promelas		
15625-89-5	2,2-bis(acryloyloxymethyl)butyl acrylate, trimethylolpropane triacrylate					
	Acute algae toxicity	ErC50 4,86 mg/l	96 h	Desmodesmus subspicatus.		
	Acute crustacea toxicity	EC50 19,9 mg/l	48 h	Daphnia magna (Big water flea)		

### 12.2. Persistence and degradability

The product has not been tested.

according to Regulation (EC) No 1907/2006

### medicalprint® mould 2.0

Revision date: 23.10.2019

Product code: 1093

Page 9 of 12

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
66492-51-1	2-Propenoic acid, (5-ethyl-1,3-dioxan-5-yl)methyl ester			
	Evidence for inherent biodegradability.	28%	28	
42594-17-2	Tricyclodecane dimethanol diacrylate			
	OECD 301F/ ISO 9408/ EEC 92/69/V, C.4-D	28%	28	
	Not readily biodegradable (according to OECD criteria)			
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide			
		0-10%	28	
	Not readily biodegradable (according to OECD criteria)			
868-77-9	2-hydroxyethyl methacrylate			
	84	%	28	
	Leicht biologisch abbaubar			
15625-89-5	2,2-bis(acryloyloxymethyl)butyl acrylate, trimethylolpropane triacrylate			
		86%	28	
	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
66492-51-1	2-Propenoic acid, (5-ethyl-1,3-dioxan-5-yl)methyl ester	1,9
42594-17-2	Tricyclodecane dimethanol diacrylate	4,64
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	3,1
868-77-9	2-hydroxyethyl methacrylate	0,47
15625-89-5	2,2-bis(acryloyloxymethyl)butyl acrylate, trimethylolpropane triacrylate	0,67

### BCF

CAS No	Chemical name	BCF	Species	Source
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	47-55	Cyprinus carpio (Common Carp)	

### 12.4. Mobility in soil

The product has not been tested.

### 12.5. Results of PBT and vPvB assessment

Not identified as PBT/ vPvB substances

### 12.6. 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

#### Advice on disposal

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

according to Regulation (EC) No 1907/2006

### medicalprint® mould 2.0

Revision date: 23.10.2019

Product code: 1093

Page 10 of 12

substance itself.

## SECTION 14: Transport information

### Land transport (ADR/RID)

<b>14.1. UN number:</b>	UN 3082
<b>14.2. UN proper shipping name:</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. Contains: 2-Propenoic acid, (5-ethyl-1,3-dioxan-5-yl)methyl ester
<b>14.3. Transport hazard class(es):</b>	9
<b>14.4. Packing group:</b>	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:	-

### Marine transport (IMDG)

<b>14.1. UN number:</b>	UN 3082
<b>14.2. UN proper shipping name:</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. Contains: 2-Propenoic acid, (5-ethyl-1,3-dioxan-5-yl)methyl ester
<b>14.3. Transport hazard class(es):</b>	9
<b>14.4. Packing group:</b>	III
Hazard label:	9
Marine pollutant:	yes
Special Provisions:	274, 335, 969
Limited quantity:	5 L
Excepted quantity:	E1
EmS:	F-A, S-F

### Air transport (ICAO-TI/IATA-DGR)

<b>14.1. UN number:</b>	UN 3082
<b>14.2. UN proper shipping name:</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. Contains: 2-Propenoic acid, (5-ethyl-1,3-dioxan-5-yl)methyl ester
<b>14.3. Transport hazard class(es):</b>	9
<b>14.4. Packing group:</b>	III
Hazard label:	9
Special Provisions:	A97 A158 A197
Limited quantity Passenger:	30 kg G
Passenger LQ:	Y964
Excepted quantity:	E1
IATA-packing instructions - Passenger:	964
IATA-max. quantity - Passenger:	450 L
IATA-packing instructions - Cargo:	964
IATA-max. quantity - Cargo:	450 L

### Other applicable information (air transport)

Flash point: ...

### 14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: yes

according to Regulation (EC) No 1907/2006

### medicalprint® mould 2.0

Revision date: 23.10.2019

Product code: 1093

Page 11 of 12

#### 14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

#### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

No dangerous good in sense of this transport regulation.

### SECTION 15: Regulatory information

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

##### EU regulatory information

Information according to 2012/18/EU  
(SEVESO III):

E2 Hazardous to the Aquatic Environment

##### National regulatory information

Employment restrictions:

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

Water contaminating class (D):

3 - highly water contaminating

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%

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

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### medicalprint® mould 2.0

Revision date: 23.10.2019

Product code: 1093

Page 12 of 12

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

@1602.B016012

#### Classification for mixtures and used evaluation method according to Regulation (EC) No. 1272/2008 [CLP]

Classification	Classification procedure
Skin Irrit. 2; H315	Calculation method
Eye Irrit. 2; H319	Calculation method
Skin Sens. 1A; H317	Calculation method
STOT SE 3; H335	Calculation method
Aquatic Chronic 2; H411	Calculation method

#### Relevant H and EUH statements (number and full text)

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H361f	Suspected of damaging fertility.
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.

#### Further Information

The information is based on present level of our knowledge. It does not, however, give assurances 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.)*