

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Date of issue: 23-4-2018 Version: 1.0

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

**Product identifier** 

Product form : Mixture

: NextDent SG Orange Product name Product group : Trade product

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

#### 1.2.1. Relevant identified uses

Main use category : Professional use

: Manufacture of 3D-printed applications for the dental industry Use of the substance/mixture

Use of the substance/mixture : Dentistry

Title	Use descriptors
NextDent SG Orange	SU20

Full text of use descriptors: see section 16

#### 1.2.2. **Uses advised against**

No additional information available

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

Vertex Dental Centurionbaan 190 3769 AV Soesterberg - The Netherlands T+31 886160400

info@vertex-dental.com - www.vertex-dental.com

## **Emergency telephone number**

: (Only for the purpose of informing medical personnel in cases of accidental intoxications. The Emergency number emergency phone number is 24 hours/day available.)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	National Poisons Information Service (Birmingham Centre)	Dudley Road B18 7QH Birmingham	0344 892 0111	

## **SECTION 2: Hazards identification**

### Classification of the substance or mixture

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

Skin sensitisation, Category 1 H317 Hazardous to the aquatic environment — H411

Chronic Hazard, Category 2

Full text of H statements: see section 16

### Adverse physicochemical, human health and environmental effects

No additional information available

### **Label elements**

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

Hazard pictograms (CLP)



GHS09

Signal word (CLP) : Warning

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl Hazardous ingredients

GHS07

bismethacrylate; phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide

Hazard statements (CLP) H317 - May cause an allergic skin reaction.

H411 - Toxic to aquatic life with long lasting effects.

P280 - Wear protective gloves. Precautionary statements (CLP)

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

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P363 - Wash contaminated clothing before reuse.

P273 - Avoid release to the environment.

P391 - Collect spillage.

P501 - Dispose of contents/container to an approved waste disposal plant.

#### 2.3. Other hazards

No additional information available

## **SECTION 3: Composition/information on ingredients**

#### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	% w/w (% w/w)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethoxylated bisphenol A dimethacrylate	(CAS-No.) 41637-38-1 (EC-No.) 609-946-4	>= 75	Aquatic Chronic 4, H413
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	(CAS-No.) 72869-86-4 (EC-No.) 276-957-5 (REACH-no) 01-2120751202-68	30 - 50	Skin Sens. 1B, H317 Aquatic Chronic 2, H411
phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	(CAS-No.) 162881-26-7 (EC-No.) 423-340-5 (EC Index-No.) 015-189-00-5 (REACH-no) 01-2119489401-38	< 10	Skin Sens. 1, H317 Aquatic Chronic 4, H413

Full text of H-statements: see section 16

### **SECTION 4: First aid measures**

### 4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical

advice (show the label where possible).

First-aid measures after inhalation : Assure fresh air breathing. Allow the victim to rest.

First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. If skin irritation or rash occurs: Get medical advice/attention. Wash

contaminated clothing before reuse.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

### 4.2. Most important symptoms and effects, both acute and delayed

No additional information available

## 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

## **SECTION 5: Firefighting measures**

## 5.1. Extinguishing media

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media : Do not use a heavy water stream.

### 5.2. Special hazards arising from the substance or mixture

No additional information available

### 5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any

chemical fire. Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

### **SECTION 6: Accidental release measures**

## 6.1. Personal precautions, protective equipment and emergency procedures

### 6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

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### 6.1.2. For emergency responders

No additional information available

### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Soak up

: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Store away from other materials.

### away nom other mater

Concerning personal protective equipment to use, see section 8. Concerning disposal elimination after cleaning, see section 13.

## **SECTION 7: Handling and storage**

Reference to other sections

#### 7.1. Precautions for safe handling

Precautions for safe handling

: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation

of vapou

Hygiene measures : Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out

of the workplace. Wash contaminated clothing before reuse.

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

Storage conditions

: Keep only in original container. Keep container closed when not in use. To avoid the risks of fires, all contaminated materials should be stored in purpose-built containers or in metal containers with tight-fitting self-closing lids.

Incompatible products : Strong bases. Strong acids.
Incompatible materials : Sources of ignition. Direct sunlight.

### 7.3. Specific end use(s)

No additional information available

### **SECTION 8: Exposure controls/personal protection**

## 8.1. Control parameters

Ethoxylated bisphenol A dimethacrylate (41637-38-1)			
DNEL/DMEL (Workers)			
Long-term - systemic effects, dermal	2 mg/kg bodyweight/day		
Long-term - systemic effects, inhalation	3,52 mg/m³		
DNEL/DMEL (General population)			
Long-term - systemic effects,oral	0,5 mg/kg bodyweight/day		
Long-term - systemic effects, inhalation	0,87 mg/m³		
Long-term - systemic effects, dermal	1 mg/kg bodyweight/day		
phenyl bis(2,4,6-trimethylbenzoyl)-phosphine	oxide (162881-26-7)		
DNEL/DMEL (Workers)			
Acute - systemic effects, dermal	3,33 mg/kg bodyweight/day		
Acute - systemic effects, inhalation	7,84 mg/m³		
Long-term - systemic effects, dermal	3,33 mg/kg bodyweight/day		
Long-term - systemic effects, inhalation	7,84 mg/m³		
DNEL/DMEL (General population)			
Acute - systemic effects, dermal	1,67 mg/kg bodyweight		
Acute - systemic effects, inhalation	3,92 mg/m³		
Acute - systemic effects, oral	1,67 mg/kg bodyweight		
Long-term - systemic effects,oral	1,5 mg/kg bodyweight/day		
Long-term - systemic effects, inhalation	1,93 mg/m³		
Long-term - systemic effects, dermal	1,5 mg/kg bodyweight/day		
PNEC (Water)			
PNEC aqua (freshwater)	0,0008 - 0,001 mg/l		
PNEC aqua (marine water)	0,0008 - 0,001		
PNEC aqua (intermittent, marine water)	0,0008 - 0,001 mg/l		
PNEC (Sediment)			
PNEC sediment (freshwater)	0,712 mg/kg bw		
PNEC sediment (marine water)	0,712 mg/kg bw		
PNEC (Soil)			
PNEC soil	20 mg/kg bw		

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phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide (162881-26-7)			
PNEC (STP)			
PNEC sewage treatment plant	1 mg/l		
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate (72869-86-4)			
DNEL/DMEL (Workers)			
Long-term - systemic effects, dermal	1,3 mg/kg bodyweight/day		
Long-term - systemic effects, inhalation	3,3 mg/m³		
DNEL/DMEL (General population)			
Long-term - systemic effects,oral	0,3 mg/kg bodyweight/day		
Long-term - systemic effects, inhalation	0,6 mg/m³		
Long-term - systemic effects, dermal	0,7 mg/kg bodyweight/day		
PNEC (Water)			
PNEC aqua (freshwater)	0,01 mg/l		
PNEC aqua (marine water)	0,001 mg/l		
PNEC aqua (intermittent, freshwater)	0,1 mg/l		
PNEC aqua (intermittent, marine water)	0,1 mg/l		
PNEC (Sediment)			
PNEC sediment (freshwater)	4,56 mg/kg bw		
PNEC sediment (marine water)	0,46 mg/kg bw		
PNEC (Soil)			
PNEC soil	0,91 mg/kg bw		
PNEC (STP)			
PNEC sewage treatment plant	3,61 mg/l		
8.2. Exposure controls			

## Hand protection:

Wear suitable gloves resistant to chemical penetration. The protective gloves to be used must comply with the specifications of EC directive 89/686/EEC and the resultant standard EN 374. penetration time (maximum wearing period): > 480 m. Suitable material: Nitrile rubber, Chloroprene rubber, Polyvinylchloride (PVC). Layer thickness: 0,4 mm - 0,5 mm - 0,7 mm

## Eye protection:

Wear eye glasses with side protection according to EN 166.

### Skin and body protection:

Wear suitable protective clothing

### Respiratory protection:

No personal breathing protective equipment is normally required. In case of inadequate ventilation wear respiratory protection. particle filter device (DIN EN 143)

### Personal protective equipment symbol(s):







## **Environmental exposure controls:**

Use appropriate container to avoid environmental contamination.

## Other information:

Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes.

## **SECTION 9: Physical and chemical properties**

## 9.1. Information on basic physical and chemical properties

Physical state : Liquid

Colour : transparent. orange.

Odour : Ester.

Odour threshold : No data available pH : No data available Relative evaporation rate (butylacetate=1) : No data available Melting point : No data available

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Freezing point : No data available

Boiling point : > 200 °C

Flash point : No data available

Auto-ignition temperature : 375 °C

Decomposition temperature : No data available Flammability (solid, gas) : No data available Vapour pressure : No data available Relative vapour density at 20 °C : No data available

Relative density : 1,1 - 1,2 Relative density, liquid (water=1)

Solubility : Soluble in organic solvents.

Water: insoluble in water

Log Pow : No data available
Viscosity, kinematic : No data available
Viscosity, dynamic : 0,9 - 1,1 Pa.s
Explosive properties : No data available
Oxidising properties : No data available
Explosive limits : No data available

9.2. Other information

VOC content : 0 %

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

Not established.

## 10.3. Possibility of hazardous reactions

Not established.

### 10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

## 10.5. Incompatible materials

No additional information available

## 10.6. Hazardous decomposition products

No additional information available

## **SECTION 11: Toxicological information**

### 11.1. Information on toxicological effects

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

Ethoxylated bisphenol A dimethacrylate (41637-38-1)			
LD50 oral rat 2000 mg/kg			
LD50 dermal rat 2000 mg/kg			

phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide (162881-26-7)			
LD50 oral rat 2000 mg/kg			
LD50 dermal rat 2000 mg/kg			

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate (72869-86-4)			
LD50 oral rat 5000 mg/kg			
LD50 dermal rat	2000 mg/kg		

Skin corrosion/irritation : Not classified Serious eye damage/irritation : Not classified

Respiratory or skin sensitisation : May cause an allergic skin reaction.

Germ cell mutagenicity : Not classified Carcinogenicity : Not classified Reproductive toxicity : Not classified

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STOT-single exposure : Not classified STOT-repeated exposure : Not classified

Ethoxylated bisphenol A dimethacrylate (41637-38-1)		
NOAEL (oral, rat, 90 days) 300 mg/kg bodyweight/day		
phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide (162881-26-7)		
NOAEL (oral, rat, 90 days) 1000 mg/kg bodyweight/day		
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate (72869-86-4)		
NOAEL (oral, rat, 90 days) 100 - 300 mg/kg bodyweight/day		

Aspiration hazard : Not classified

## SECTION 12: Ecological information

## 12.1. Toxicity

Ecology - general : Avoid release to the environment.

Acute aquatic toxicity : Not classified

Chronic aquatic toxicity : Toxic to aquatic life with long lasting effects.

Ethoxylated bisphenol A dimethacrylate (41637-38-1)			
NOEC (chronic)	14,3 mg/l 28 d		
phenyl bis(2,4,6-trimethylbenzoyl)-phosphine	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide (162881-26-7)		
LC50 fishes	0,09 mg/l		
EC50 Daphnia	1,175 mg/l		
EC50 72h algae (1)	0,26 mg/l		
LOEC (chronic)	0,008 mg/l		
NOEC (chronic)	0,008 mg/l 21 d		
NOEC chronic algae	0,26 mg/l		
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate (72869-86-4)			
LC50 fishes	10,1 mg/l		
EC50 Daphnia	1,2 mg/l		
EC50 72h algae (1)	0,68 mg/l		

### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

Ethoxylated bisphenol A dimethacrylate (41637-38-1)		
Log Pow 3,43 - 5,62 @ pH 6.44		
phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide (162881-26-7)		
Log Pow 4,65 - 5,8 @ 20-22 °C and pH 7.5		
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate (72869-86-4)		
Log Pow 3 - 3,39 @ 20 °C and pH 7		

## 12.4. Mobility in soil

No additional information available

## 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Other adverse effects

Additional information : Avoid release to the environment.

## **SECTION 13: Disposal considerations**

## 13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to official regulations.

Product/Packaging disposal recommendations : Can be dumped in according to local regulations.

Ecology - waste materials : Avoid release to the environment.

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## **SECTION 14: Transport information**

In accordance with ADR / RID / IMDG / IATA / ADN

accordance man, azit, ita	D / IIVIDG / IATA / ADIN			
ADR	IMDG	IATA	ADN	RID
14.1. UN number				
3082	3082	3082	3082	3082
14.2. UN proper shipping	ng name			
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.	Environmentally hazardous substance, liquid, n.o.s.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
Transport document descr	iption (ADR)			
UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (7,7,9(or 7,9,9)- trimethyl-4,13-dioxo-3,14- dioxa-5,12- diazahexadecane-1,16-diyl bismethacrylate), 9, III, (-)	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S., 9, III, MARINE POLLUTANT	UN 3082 Environmentally hazardous substance, liquid, n.o.s., 9, III	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S., 9, III	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S., 9, III
14.3. Transport hazard	• • •			
9	9	9	9	9
14.4. Packing group				
III	III	III	III	III
14.5. Environmental hazards				
Dangerous for the environment : Yes	Dangerous for the environment : Yes Marine pollutant : Yes	Dangerous for the environment : Yes	Dangerous for the environment : Yes	Dangerous for the environment : Yes
No supplementary information available				

#### 14.6. Special precautions for user

### - Overland transport

Classification code (ADR) : M6

Special provisions (ADR) : 274, 335, 375, 601

Limited quantities (ADR) : 51 Excepted quantities (ADR) : E1

: P001, IBC03, LP01, R001 Packing instructions (ADR)

Special packing provisions (ADR) : PP1 Mixed packing provisions (ADR) : MP19 Portable tank and bulk container instructions : T4 (ADR)

Portable tank and bulk container special

provisions (ADR)

: TP1, TP29

Tank code (ADR) : LGBV Vehicle for tank carriage : AT Transport category (ADR) : 3 Special provisions for carriage - Packages : V12

(ADR) Special provisions for carriage - Loading,

unloading and handling (ADR)

Hazard identification number (Kemler No.) : 90

Orange plates

90 3082

: CV13

Tunnel restriction code (ADR) EAC code : •3Z

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### - Transport by sea

Special provisions (IMDG) : 274, 335, 969 Packing instructions (IMDG) : P001, LP01 Special packing provisions (IMDG) : PP1 IBC packing instructions (IMDG) : IBC03 Tank instructions (IMDG) : T4 Tank special provisions (IMDG) : TP2, TP29 EmS-No. (Fire) : F-A EmS-No. (Spillage) : S-F Stowage category (IMDG) : A

### - Air transport

PCA Excepted quantities (IATA) : E1 PCA Limited quantities (IATA) : Y964 PCA limited quantity max net quantity (IATA) : 30kgG PCA packing instructions (IATA) : 964 PCA max net quantity (IATA) : 450L CAO packing instructions (IATA) : 964 CAO max net quantity (IATA) : 450L

Special provisions (IATA) : A97, A158, A197

ERG code (IATA)

### - Inland waterway transport

Classification code (ADN) : M6

: 274, 335, 375, 601 Special provisions (ADN)

Limited quantities (ADN) : 5 L Excepted quantities (ADN) : E1 Carriage permitted (ADN) : T : PP Equipment required (ADN) Number of blue cones/lights (ADN) : 0

### - Rail transport

Classification code (RID) : M6

Special provisions (RID) : 274, 335, 375, 601

Excepted quantities (RID)

Packing instructions (RID) : P001, IBC03, LP01, R001

Special packing provisions (RID) : PP1 Mixed packing provisions (RID) : MP19 Portable tank and bulk container instructions : T4

(RID)

Portable tank and bulk container special : TP1, TP29

provisions (RID)

Tank codes for RID tanks (RID) : LGBV Transport category (RID) : 3 Special provisions for carriage - Packages : W12

Special provisions for carriage - Loading,

: CW13, CW31

unloading and handling (RID)

Colis express (express parcels) (RID) : CE8 Hazard identification number (RID) : 90

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

Not applicable

## **SECTION 15: Regulatory information**

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

#### **EU-Regulations** 15.1.1.

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

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3(b) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10	NextDent SG Orange - 7,7,9(or 7,9,9)-trimethyl- 4,13-dioxo-3,14-dioxa-5,12-diazahexadecane- 1,16-diyl bismethacrylate
3(c) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard class 4.1	NextDent SG Orange - Ethoxylated bisphenol A dimethacrylate - 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

VOC content : 0 %

### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## **SECTION 16: Other information**

Data sources	: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE
	COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and
	mixtures, amending and repealing Directives 67/548/FEC and 1999/45/FC, and amending

Regulation (EC) No 1907/2006.

Other information : DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or

believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable.

## Full text of H- and EUH-statements:

Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2		
Aquatic Chronic 4	Hazardous to the aquatic environment — Chronic Hazard, Category 4		
Skin Sens. 1	Skin sensitisation, Category 1		
Skin Sens. 1B	Skin sensitisation, category 1B		
H317	May cause an allergic skin reaction.		
H411	Toxic to aquatic life with long lasting effects.		
H413	May cause long lasting harmful effects to aquatic life.		

## Full text of use descriptors

SU20	Health services					
Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:						
Skin Sone 1	H317	Calculation method				

Skin Sens. 1	H317	Calculation method
Aquatic Chronic 2	H411	Calculation method

## SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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