Telefax: +41 71 775 80 99



# **Safety Data Sheet**

## according to UK REACH Regulation

## apt unibond

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

## 1.1. Product identifier

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

#### Use of the substance/mixture

Saremco cements and auxiliary bonding promotors are intended for the indirect reconstruction or correction of functionally compromised natural dentition

# Uses advised against

None.

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

Company name: Saremco Dental AG
Street: Gewerbestrasse 4
Place: CH-9445 Rebstein
Telephone: +41 71 775 80 90

e-mail: info@saremco.ch

Contact person: Dr. Christoph Evers Telephone: +41 71 775 80 60

e-mail: Christoph.evers@saremco.ch

Internet: www.saremco.ch

Responsible Department: Vigilance

1.4. Emergency telephone CH: 145

<u>number:</u> Ausland: +41 44 251 51 51

# **SECTION 2: Hazards identification**

## 2.1. Classification of the substance or mixture

# **GB CLP Regulation**

Skin Irrit. 2; H315 Eye Irrit. 2; H319 Skin Sens. 1; H317 STOT SE 3; H335 Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

## 2.2. Label elements

# **GB CLP Regulation**

## Hazard components for labelling

10-Methacryloyl-oxydecyl-dihydrogenphosphat

BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE, BISEMA

aromatic urethane methacrylate, NCO monomer resin

Signal word: Warning

Pictograms:



#### **Hazard statements**

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.
 H319 Causes serious eye irritation.
 H335 May cause respiratory irritation.



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H412 Harmful to aquatic life with long lasting effects.

## **Precautionary statements**

P264 Wash hands thoroughly after handling.

P280 Wear protective gloves.

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

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P501 Dispose of contents/container to an appropriate recycling or disposal facility.

## 2.3. Other hazards

No information available.

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

## 3.2. Mixtures

## **Hazardous components**

CAS No	Chemical name				
	EC No	Index No	REACH No		
	Classification (GB CLP Regulation)				
64-17-5	ethanol; ethyl alcohol				
	200-578-6	603-002-00-5			
	Flam. Liq. 2, Eye Irrit. 2; H225 H31	9			
85590-00-7	10-Methacryloyl-oxydecyl-dihydrog	enphosphat		25 - < 50 %	
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3	; H315 H319 H335			
41637-38-1	BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE, BISEMA				
	609-946-4				
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335				
126646-17-1	aromatic urethane methacrylate, NCO monomer resin				
	682-529-2				
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335				
	Acrylpolymer; Degacryl 4779 L				
	Eye Irrit. 2; H319				
128-37-0	Butylated hydroxitoluene	0.1 - < 1 %			
	204-881-4				
	Aquatic Chronic 1; H410				

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

## Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc.	Specific Conc. Limits, M-factors and ATE	
64-17-5	200-578-6	ethanol; ethyl alcohol	25 - < 50 %
	inhalation: LC50 = 95,6 mg/l (vapours); oral: LD50 = 6200 mg/kg		
85590-00-7		10-Methacryloyl-oxydecyl-dihydrogenphosphat	25 - < 50 %
	oral: LD50 = >	oral: LD50 = > 2000 mg/kg	
128-37-0	204-881-4	Butylated hydroxitoluene	0.1 - < 1 %
	oral: LD50 = >6000 mg/kg		

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

## 4.1. Description of first aid measures





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#### 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

Observe risk of aspiration if vomiting occurs. Rinse mouth immediately and drink 1 glass of of water.

## 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

#### 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

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

#### Other information

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



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## Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Avoid dust formation. Do not breathe dust.

#### 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. 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 or drink.

## 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

No special measures are necessary.

## 7.3. Specific end use(s)

Saremco Dental-Haftvermittler fördern die Haftung von direktem oder indirektem Zahnersatz zur Rekonstruktion oder Korrektur von funktionell beeinträchtigten natürlichen Zähnen.

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

# 8.1. Control parameters

# **Exposure limits (EH40)**

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
128-37-0	2,6-Di-tert-butyl-p-cresol	-	10		TWA (8 h)	WEL
64-17-5	Ethanol	1000	1920		TWA (8 h)	WEL

## 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.

## Individual protection measures, such as personal protective equipment

## 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.

#### Skin protection

Use of protective clothing.



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## 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: yellow

Melting point/freezing point:

Boiling point or initial boiling point and

not determined
not determined

boiling range:

Flammability: not determined Lower explosion limits: not determined Upper explosion limits: not determined > 150 °C Flash point: Auto-ignition temperature: not determined Decomposition temperature: not determined not determined pH-Value: 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:

Vapour pressure:

Density (at 20 °C):

Relative vapour density:

not determined

1.3 g/cm³

not determined

#### 9.2. Other information

## Information with regard to physical hazard classes

Explosive properties

The product is not: Explosive.

Oxidizing properties

The product is not: oxidising.

## Other safety characteristics

Evaporation rate: not determined 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

No known hazardous reactions.

## 10.4. Conditions to avoid

none

# 10.5. Incompatible materials

No information available.

# 10.6. Hazardous decomposition products

No known hazardous decomposition products.



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## **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.

CAS No	Chemical name					
	Exposure route	Dose		Species	Source	Method
64-17-5	ethanol; ethyl alcohol					
	oral	LD50 mg/kg	6200	Ratte	IUCLID	
	inhalation (4 h) vapour	LC50	95,6 mg/l	Ratte	RTECS	
85590-00-7	10-Methacryloyl-oxydecyl-dihydrogenphosphat					
	oral	LD50 mg/kg	> 2000	Rat		
128-37-0	Butylated hydroxitoluene					
	oral	LD50 mg/kg	>6000	rat		OECD 401

## Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

## Sensitising effects

May cause an allergic skin reaction. (BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE, BisEMA; aromatic urethane methacrylate, NCO monomer resin)

## Carcinogenic/mutagenic/toxic effects for reproduction

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

## STOT-single exposure

May cause respiratory irritation. (10-Methacryloyl-oxydecyl-dihydrogenphosphat)

## 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.

# 11.2. Information on other hazards

## **Further information**

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

# **SECTION 12: Ecological information**

# 12.1. Toxicity

Harmful to aquatic life with long lasting effects.

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method
64-17-5	ethanol; ethyl alcohol					
	Acute crustacea toxicity	EC50 9268 - 14221 mg/l	48 h	Daphnia magna	IUCLID	

# 12.2. Persistence and degradability

The product has not been tested.

## 12.3. Bioaccumulative potential

The product has not been tested.



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#### Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
64-17-5	ethanol; ethyl alcohol	-0,31

## 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.

The product has not been tested.

# 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 substance itself.

## **SECTION 14: Transport information**

#### Land transport (ADR/RID)

14.1. UN number or ID number:No dangerous good in sense of this transport regulation.14.2. UN proper shipping name:No dangerous good in sense of this transport regulation.14.3. Transport hazard class(es):No dangerous good in sense of this transport regulation.14.4. Packing group:No dangerous good in sense of this transport regulation.

## Marine transport (IMDG)

# Other applicable information (marine transport)

No dangerous good in sense of these transport regulations.

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

## Other applicable information (air transport)

No dangerous good in sense of these transport regulations.

## 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 40



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Information according to 2012/18/EU

(SEVESO III):

Not subject to 2012/18/EU (SEVESO III)

**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): - - non-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%

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 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

@1605.B000001

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

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Classification	Classification procedure			
Skin Irrit. 2; H315	Calculation method			
Eye Irrit. 2; H319	Calculation method			
Skin Sens. 1; H317	Calculation method			
STOT SE 3; H335	Calculation method			
Aquatic Chronic 3; H412	Calculation method			



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

H225	Highly flammable liquid and vapour.
11223	I IIUI IIV IIai III IIabie IIUulu ai iu vaboui.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

Very toxic to aquatic life with long lasting effects.
 Harmful to aquatic life with long lasting effects.

## **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.)