



Material Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product and must be read in conjunction with the Safety Data Sheet (SDS) attached

Product Name: Simplicity Kit - Optibond Universal, Simplishade & Maxcem

Manufacturer: Kerr Italia S.r.l.

SDS Expiry: 9 October 2027

Supplier Details: Henry Schein New Zealand

243-249 Bush Road, Rosedale, Auckland, 0632 PO Box 101 140, North Shore, Auckland 0745

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Emergency Contacts: Poisons/Hazardous Chemical Info Centre –

0800POISON/0800764766 (24 Hours) Phone 111 for Fire, Ambulance or Police

HSNO Class/Category: 3 / 6 / 9

HSNO Group Standard: Dental Products Flammable Group Standard 2020

HSR002556

Statements/Pictograms: As per attached Safety Data Sheet (SDS)

Date Prepared: This coversheet was prepared – August 2025

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.





## Maxcem Elite Chroma Base

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Issue date: 02/09/2022 Version: 1.0

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

#### 1.1. Product identifier

Product form Mixture

Product name Maxcem Elite Chroma Base

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

#### Relevant identified uses

Main use category : Professional use

Use of the substance/mixture : Preparation intended for dental medical use

Function or use category : Dental materials.

#### Uses advised against

No additional information available

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

#### Supplier

Kerr Italia S.r.I. Via Passanti, 174 Scafati (SA) 84018 (Italy)

T +39 081 850 3511 / Information Phone Number: 1-800-841-1428 (Customer Service)

safety@envistaco.com

#### 1.4. Emergency telephone number

: CHEMTREC® Emergency Call Center. Emergency Telephone Number (for USA only) 001-800-424-9300 Emergency number International and Maritime Telephone Number +1 (703) 527-3887

Comment Country Official advisory body Address **Emergency number** Gibraltar **GHA Call Centre** Harbour Views Road +350 200 79700 Zone 2, Level3, St Bernard's Hospital +350 200 72266 Ireland National Poisons Information Centre PO Box 1297 +353 1 809 2566 (Healthcare Beaumont Hospital Beaumont Road professionals-24/7) +353 1 809 2166 (public, 8am 9 Dublin - 10pm, 7/7) Malta Medicines & Poisons Info Office Mater Dei Hospital +356 2545 6508 MSD 2090 Msida United Kingdom National Poisons Information Service Claremont Place +44 191 2606182 Hours of operation: 24hrs +44 191 2606180 (Newcastle Unit) Newcastle-upon-Tvne. Newcastle

## **SECTION 2: Hazards identification**

### 2.1. Classification of the substance or mixture

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

Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1 H317 STOT SE 3 H335

Full text of hazard classes and H-statements : see section 16

#### Adverse physicochemical, human health and environmental effects

No additional information available

## Maxcem Elite Chroma Base

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

#### 2.2. Label elements

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

Hazard pictograms (CLP)



GHS07

Signal word (CLP) : Warning

Contains : 2-hydroxyethyl methacrylate, mequinol; 4-methoxyphenol; hydroquinone monomethyl ether

Hazard statements (CLP) : H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction. H319 - Causes serious eye irritation. H335 - May cause respiratory irritation. P261 - Avoid breathing mist, vapours, gas.

Precautionary statements (CLP) : P261 - Avoid breathing mist, vapours, gas.
P280 - Wear eye protection, protective gloves.

P302+P352 - IF ON SKIN: Wash with plenty of soap and water.

P304+P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for

breathing.

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

lenses, if present and easy to do. Continue rinsing.

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention.

EUH-statements : EUH211 - Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray

or mist.

Extra phrases : The product is seen as a medical device (Directive 90/385/EEC, 93/42/EEC, 98/79/EC) and therefore not

subject to labelling (EU-regulation 1272/2008, article 1, paragraph 5d).

A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety

Information Sheet has been created on a voluntary basis.

#### 2.3. Other hazards

Other hazards which do not result in classification : None under normal conditions. This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

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

## 3.1. Substances

Not applicable

#### 3.2. Mixtures

Name	Product identifier	Conc. (% w/w)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
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) 01-2119408252-52	20 – 25	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335
Ytterbium trifluorid	(CAS-No.) 13760-80-0 (EC-No.) 237-354-2 (REACH-no) N/A	10 – 20	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
2-hydroxyethyl methacrylate (Note D)	(CAS-No.) 868-77-9 (EC-No.) 212-782-2 (EC Index-No.) 607-124-00-X (REACH-no) 01-2119490169-29	2-5	Eye Irrit. 2, H319 Skin Irrit. 2, H315 Skin Sens. 1, H317
2-hydroxy-1,3-propanediyl bismethacrylate	(CAS-No.) 1830-78-0 (EC-No.) 217-388-4 (REACH-no) N/A	2-5	Eye Irrit. 2, H319 Skin Irrit. 2, H315 STOT SE 3, H335

## Maxcem Elite Chroma Base

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica substance with national workplace exposure limit(s) (GB); substance with a Community workplace exposure limit	(CAS-No.) 68909-20-6 (EC-No.) 272-697-1 (REACH-no) n/a	1 – 5	Not classified
mequinol; 4-methoxyphenol; hydroquinone monomethyl ether substance with national workplace exposure limit(s) (IE)	(CAS-No.) 150-76-5 (EC-No.) 205-769-8 (EC Index-No.) 604-044-00-7 (REACH-no) 01-2119541813-40	0.1 – 1	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Eye Irrit. 2, H319 Skin Sens. 1, H317
titanium dioxide substance with national workplace exposure limit(s) (GB, IE)	(CAS-No.) 13463-67-7 (EC-No.) 236-675-5 (EC Index-No.) 022-006-00-2 (REACH-no) 01-2119489379-17	0.1 – 1	Not classified
Iron hydroxide oxide yellow substance with national workplace exposure limit(s) (GB, IE)	(CAS-No.) 51274-00-1 (EC-No.) 257-098-5	0.1 – 1	Not classified

Note D: Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier must state on the label the name of the substance followed by the words 'non-stabilised'.

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

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

#### 4.1. Description of first aid measures

First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you

feel unwell.

First-aid measures after skin contact : Gently wash with plenty of soap and water. Wash contaminated clothing before reuse. If skin irritation or

rash occurs: Get medical advice/attention.

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. Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/effects after inhalation : May cause respiratory irritation.

Symptoms/effects after skin contact : Causes skin irritation. May cause an allergic skin reaction.

Symptoms/effects after eye contact : Causes serious eye irritation.

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

Treat symptomatically. In all cases of doubt, or when symptoms persist, seek medical attention.

## **SECTION 5: Firefighting measures**

### 5.1. Extinguishing media

First-aid measures after ingestion

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. 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

Fire hazard : Non-flammable.

Explosion hazard : Product is not explosive.

Hazardous decomposition products in case of fire : Carbon dioxide. Carbon monoxide. Nitrogen oxides. Phosphorus oxides (POx). Halogenated

compounds. metallic oxide.

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 personal protective equipment, including respiratory protection

(EN137).

## Maxcem Elite Chroma Base

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

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

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

General measures : Avoid contact with skin and eyes. Concerning personal protective equipment to use, see section 8.

6.1.1. For non-emergency personnel

Protective equipment : See Section 8.

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup and emergency crew with proper protection.

Emergency procedures : Ventilate area

#### 6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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

For containment : Collect all waste in suitable and labelled containers and dispose according to local legislation.

Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage.

Store away from other materials.

#### 6.4. Reference to other sections

For further information refer to section 13. See Section 8. Exposure controls and personal protection.

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

### 7.1. Precautions for safe handling

Precautions for safe handling : Keep container tightly closed. Avoid contact with skin and eyes. Provide good ventilation in process area

to prevent formation of vapour. Avoid breathing mist, spray, vapours.

Hygiene measures : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and

when leaving work. Do not eat, drink or smoke when using this product.

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

Storage conditions : Store in dry protected location to prevent any moisture contact. Keep container tightly closed. Keep cool.

Keep only in original container. Keep away from ignition sources. Protect from sunlight. Store in a well-

ventilated place.

Incompatible materials : Oxidizing substances. reducing materials. Organic peroxides. Amines.

Storage area : Store in a well-ventilated place.

#### 7.3. Specific end use(s)

No additional data.

## SECTION 8: Exposure controls/personal protection

## 8.1. Control parameters

### 8.1.1 National occupational exposure and biological limit values

mequinol; 4-methoxyphenol; hydroquinone monomethyl ether (150-76-5)	
Ireland - Occupational Exposure Limits	
Local name	4-Methoxyphenol [Mequinol]
OEL TWA [1]	5 mg/m³
Regulatory reference	Chemical Agents Code of Practice 2021

titanium dioxide (13463-67-7)	
Ireland - Occupational Exposure Limits	
Local name	Titanium dioxide
OEL TWA [1]	10 mg/m³ total inhalable dust 4 mg/m³ respirable dust
Regulatory reference	Chemical Agents Code of Practice 2021

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United Kingdom - Occupational Exposure Limits	
Local name	Titanium dioxide
WEL TWA (OEL TWA) [1]	10 mg/m³ total inhalable 4 mg/m³ respirable
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

Iron hydroxide oxide yellow (51274-00-1)		
Ireland - Occupational Exposure Limits		
Local name	Iron salts (as Fe)	
OEL TWA [1]	1 mg/m³	
OEL STEL	2 mg/m³	
Regulatory reference	Chemical Agents Code of Practice 2021	
United Kingdom - Occupational Exposure Limits		
Local name	Iron salts	
WEL TWA (OEL TWA) [1]	1 mg/m³ (as Fe)	
WEL STEL (OEL STEL)	2 mg/m³ (as Fe)	
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE	

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (68909-20-6)	
United Kingdom - Occupational Exposure Limits	
Local name	Silica, amorphous
WEL TWA (OEL TWA) [1]	6 mg/m³ inhalable dust 2.4 mg/m³ respirable dust
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

## 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

## 8.1.4. DNEL and PNEC

No additional information available

## 8.1.5. Control banding

No additional information available

#### 8.2. Exposure controls

## 8.2.1. Appropriate engineering controls

## Appropriate engineering controls:

Ensure good ventilation of the work station.

#### 8.2.2. Personal protection equipment

## Personal protective equipment:

Gloves. Safety glasses.





## 8.2.2.1. Eye and face protection

## Eye protection:

Use splash goggles when eye contact due to splashing is possible. STANDARD EN 166.

## 8.2.2.2. Skin protection

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#### Skin and body protection:

Wear suitable protective clothing

#### Hand protection:

Wear protective gloves. Butylrubber protective gloves. Layer thickness: 0,2 - 0,4 mm. Breakthrough time: >480 min. STANDARD EN 374.

#### 8.2.2.3. Respiratory protection

#### Respiratory protection:

No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation. Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. Extra personal protection: A/P2 filter respirator for organic vapour and harmful dust. STANDARD: EN 140 / EN 141 / EN 136 / EN 143 / EN 405 / EN 137 / EN 147

#### 8.2.2.4. Thermal hazards

No additional information available

#### 8.2.3. Environmental exposure controls

#### Other information:

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke during use. Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment.

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

## 9.1. Information on basic physical and chemical properties

Physical state Liquid Colour Various colours. Appearance : Paste. Odour : mint. Slight. Odour threshold Not determined. Melting point Not determined Freezing point : Not determined. Boiling point : Not determined. Flammability : Product is not explosive. Explosive properties

Oxidising properties Non flammable. Not determined. **Explosive limits** Lower explosive limit (LEL) Not available Upper explosive limit (UEL) : Not available Flash point : Not determined. Auto-ignition temperature Not determined Decomposition temperature : Not determined. рΗ Viscosity, kinematic Not determined. Viscosity, dynamic Not determined. Solubility : Insoluble in water. Partition coefficient n-octanol/water (Log Kow) Not available Partition coefficient n-octanol/water (Log Pow) Vapour pressure Not determined

Vapour pressure at 50°C Not available Density Not available Relative density Relative vapour density at 20°C Not determined. Particle size Not applicable Particle size distribution Not applicable Particle shape Not applicable Particle aspect ratio Not applicable Not applicable Particle aggregation state Not applicable Particle agglomeration state Particle specific surface area Not applicable Particle dustiness Not applicable

#### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

Relative evaporation rate (butylacetate=1) : Not determined.

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## **SECTION 10: Stability and reactivity**

#### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

#### 10.2. Chemical stability

Stable under normal conditions

#### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use. No polymerization.

#### 10.4. Conditions to avoid

No flames, no sparks. Eliminate all sources of ignition. Direct sunlight. Extremely high or low temperatures.

#### 10.5. Incompatible materials

Oxidizing agent. reducing materials. Organic peroxides. Amines.

#### 10.6. Hazardous decomposition products

No decomposition if stored and used normally

## **SECTION 11: Toxicological information**

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

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

2-hydroxyethyl methacrylate (868-77-9)	
LD50 oral rat	5050 mg/kg
LD50 dermal rabbit	> 3000 mg/kg

titanium dioxide (13463-67-7)	
LD50 oral rat	> 10000 mg/kg
LC50 Inhalation - Rat (Dust/Mist)	> 6.82 mg/l/4h

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (68909-20-6)	
LD50 oral rat	> 5000 mg/kg
LD50 dermal rat	> 3000 mg/kg
LC50 Inhalation - Rat	> 2000 mg/l/4h

Skin corrosion/irritation : Causes skin irritation.

pH: Not determined.

Serious eye damage/irritation : Causes serious eye irritation.

pH: Not determined.

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

Germ cell mutagenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Carcinogenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-single exposure : May cause respiratory irritation.

2-hydroxy-1,3-propanediyl bismethacrylate (1830-78-0)	
STOT-single exposure	May cause respiratory irritation.

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Ytterbium trifluorid (13760-80-0)	
STOT-single exposure	May cause respiratory irritation.

DI-bornane-2,3-dione (10373-78-1)	
STOT-single exposure	May cause respiratory irritation.

Sodium 2,6-dichloroindophenolate hydrate (620-45-1)	
STOT-single exposure	May cause respiratory irritation.

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate (72869-86-4)	
STOT-single exposure	May cause respiratory irritation.

STOT-repeated exposure : Not classified

Additional information Based on available data, the classification criteria are not met

Aspiration hazard

Additional information Based on available data, the classification criteria are not met

Maxcem Elite Chroma Base	
Viscosity, kinematic	Not determined.

#### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

11.2.2 Other information

Potential adverse human health effects and symptoms : For further information see section 4

## **SECTION 12: Ecological information**

## 12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified Hazardous to the aquatic environment, long-term (chronic)

2-hydroxyethyl methacrylate (868-77-9)	
LC50 - Fish [1]	227 mg/l (96 hours - Pimephales promelas)
EC50 - Crustacea [1]	> 280 mg/l Daphnia magna, 48 hours

titanium dioxide (13463-67-7)	
LC50 - Fish [1]	> 1000 mg/l Fundulus heteroclitus
EC50 - Crustacea [1]	> 1000 mg/l (48 hours - Daphnia magna)

## 12.2. Persistence and degradability

Maxcem Elite Chroma Base	
Persistence and degradability	No data available.

2-hydroxyethyl methacrylate (868-77-9)	
Biodegradation	84 % (OECD 301D method)

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate (72869-86-4)	
Biodegradation	22 % (OECD 301F method)

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## 12.3. Bioaccumulative potential

Maxcem Elite Chroma Base	
Partition coefficient n-octanol/water (Log Pow)	Not determined.
Bioaccumulative potential	Not established.

2-hydroxyethyl methacrylate (868-77-9)	
Bioconcentration factor (BCF REACH)	1,3 - 1,5
Partition coefficient n-octanol/water (Log Pow)	0.47

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate (72869-86-4)	
Bioconcentration factor (BCF REACH)	1.91
Partition coefficient n-octanol/water (Log Pow)	4.69

## 12.4. Mobility in soil

Maxcem Elite Chroma Base	
Ecology - soil	Material insoluble in water.

#### 12.5. Results of PBT and vPvB assessment

M	axcem Elite Chroma Base
TI	his substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
TI	his substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

#### 12.6. Endocrine disrupting properties

No additional information available

## 12.7. Other adverse effects

Other adverse effects : None to our knowledge.
Additional information : Avoid release to the environment.

## **SECTION 13: Disposal considerations**

## 13.1. Waste treatment methods

Waste treatment methods : Must not be disposed together with household garbage. Do not allow product to reach the sewage

system.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Empty container completely.

After cleaning, recycle or dispose of at an authorised site.

European List of Waste (LoW) code : 18 01 06\* - chemicals consisting of or containing dangerous substances

## **SECTION 14: Transport information**

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

Tradeordanie Will / Bit / Timbe / Tit / Yilb /					
ADR	IMDG	IATA	ADN	RID	
14.1. UN number or ID number	14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	
14.2. UN proper shipping name	14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	
14.3. Transport hazard class(es)					
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	
14.4. Packing group					
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	

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14.5. Environmental hazards				
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available				

#### 14.6. Special precautions for user

#### Overland transport

No data available

#### Transport by sea

No data available

#### Air transport

No data available

#### Inland waterway transport

No data available

#### Rail transport

No data 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

#### 15.1.1. EU-Regulations

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

Contains no substance(s) listed on the REACH Candidate List

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

#### 15.1.2. National regulations

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/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier

#### **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/EEC and

1999/45/EC, and amending Regulation (EC) No 1907/2006.

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral) Acute toxicity (oral), Category 4

EUH211 Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist

Eye Irrit. 2 Serious eye damage/eye irritation, Category 2

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.
Skin Irrit. 2 Skin corrosion/irritation, Category 2
Skin Sens. 1 Skin sensitisation, Category 1

STOT SE 3 Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

The information in this safety data sheet is based on information from the manufacturer/supplier, present european and national legislation, and presupposes that the product is used within the specified area of application.



## Maxcem Elite Chroma Catalyst

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Issue date: 02/09/2022 Version: 1.0

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

#### 1.1. Product identifier

Product form Mixture

Product name Maxcem Elite Chroma Catalyst

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

#### Relevant identified uses

Main use category : Professional use

Use of the substance/mixture : Preparation intended for dental medical use

Function or use category : Dental materials.

#### Uses advised against

No additional information available

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

#### Supplier

Kerr Italia S.r.I. Via Passanti, 174 Scafati (SA) 84018 (Italy)

T +39 081 850 3511 / Information Phone Number: 1-800-841-1428 (Customer Service)

safety@envistaco.com

#### 1.4. Emergency telephone number

: CHEMTREC® Emergency Call Center. Emergency Telephone Number (for USA only) 001-800-424-9300 Emergency number International and Maritime Telephone Number +1 (703) 527-3887

Comment Country Official advisory body Address **Emergency number** Gibraltar **GHA Call Centre** Harbour Views Road +350 200 79700 Zone 2, Level3, St Bernard's Hospital +350 200 72266 Ireland National Poisons Information Centre PO Box 1297 +353 1 809 2566 (Healthcare Beaumont Hospital Beaumont Road professionals-24/7) +353 1 809 2166 (public, 8am 9 Dublin - 10pm, 7/7) Malta Medicines & Poisons Info Office Mater Dei Hospital +356 2545 6508 MSD 2090 Msida United Kingdom National Poisons Information Service Claremont Place +44 191 2606182 Hours of operation: 24hrs +44 191 2606180 (Newcastle Unit) Newcastle-upon-Tvne. Newcastle

## **SECTION 2: Hazards identification**

### 2.1. Classification of the substance or mixture

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

Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1 H317 STOT SE 3 H335

Full text of hazard classes and H-statements : see section 16

#### Adverse physicochemical, human health and environmental effects

No additional information available

## Maxcem Elite Chroma Catalyst

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

#### 2.2. Label elements

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

Hazard pictograms (CLP)



GHS07

Signal word (CLP) : Warning

Contains : 2-hydroxyethyl methacrylate, Propylidynetrimethanol, ethoxylated, esters with acrylic acid, (1-

methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate,  $\alpha$ ,  $\alpha$ -dimethylbenzyl

hydroperoxide; cumene hydroperoxide, 1,1,3,3-Tetramethylbutyl hydroperoxide

Hazard statements (CLP) : H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction. H319 - Causes serious eye irritation. H335 - May cause respiratory irritation. P261 - Avoid breathing vapours, gas, mist.

Precautionary statements (CLP) : P261 - Avoid breathing vapours, gas, mist.
P280 - Wear eye protection, protective gloves.

P302+P352 - IF ON SKIN: Wash with plenty of water.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing.

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention.

Extra phrases : The product is seen as a medical device (Directive 90/385/EEC, 93/42/EEC, 98/79/EC) and therefore not

subject to labelling (EU-regulation 1272/2008, article 1, paragraph 5d).

A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety

Information Sheet has been created on a voluntary basis.

For professional users only.

#### 2.3. Other hazards

Other hazards which do not result in classification : None under normal conditions. This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

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

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

Name	Product identifier	Conc. (% w/w)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-hydroxy-1,3-propanediyl bismethacrylate	(CAS-No.) 1830-78-0 (EC-No.) 217-388-4 (REACH-no) N/A	7 - 15	Eye Irrit. 2, H319 Skin Irrit. 2, H315 STOT SE 3, H335
2-hydroxyethyl methacrylate (Note D)	(CAS-No.) 868-77-9 (EC-No.) 212-782-2 (EC Index-No.) 607-124-00-X (REACH-no) 01-2119490169-29	4 – 9	Eye Irrit. 2, H319 Skin Irrit. 2, H315 Skin Sens. 1, H317
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	(CAS-No.) 1565-94-2 (EC-No.) 216-367-7 (REACH-no) N/A	3 – 8	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317
Propylidynetrimethanol, ethoxylated, esters with acrylic acid	(CAS-No.) 28961-43-5 (EC-No.) 500-066-5 (REACH-no) 01-2119489900-30	1 – 5	Eye Irrit. 2, H319 Skin Sens. 1, H317

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica substance with national workplace exposure limit(s) (GB); substance with a Community workplace exposure limit	(CAS-No.) 68909-20-6 (EC-No.) 272-697-1 (REACH-no) n/a	1 – 5	Not classified
phosphorus pentoxide substance with national workplace exposure limit(s) (GB, GI, IE, MT); substance with a Community workplace exposure limit	(CAS-No.) 1314-56-3 (EC-No.) 215-236-1 (EC Index-No.) 015-010-00-0 (REACH-no) 01-2119489912-25	0.5 - 1.5	Skin Corr. 1A, H314
2,6-Di-tert-butyl-4-methylphenol (BHT) substance with national workplace exposure limit(s) (GB, IE)	(CAS-No.) 128-37-0 (EC-No.) 204-881-4 (REACH-no) 01-2119480433-40	0.1 – 1	Aquatic Acute 1, H400 Aquatic Chronic 1, H410
α, α-dimethylbenzyl hydroperoxide; cumene hydroperoxide	(CAS-No.) 80-15-9 (EC-No.) 201-254-7 (EC Index-No.) 617-002-00-8 (REACH-no) 01-2119475796-19	0.1 – 1	Org. Perox. E, H242 Acute Tox. 4 (Oral), H302 (ATE=382 mg/kg bodyweight) Acute Tox. 4 (Dermal), H312 (ATE=1100 mg/kg bodyweight) Acute Tox. 3 (Inhalation), H331 (ATE=3 mg/l/4h) Skin Corr. 1B, H314 STOT RE 2, H373 Aquatic Chronic 2, H411
1,1,3,3-Tetramethylbutyl hydroperoxide	(CAS-No.) 5809-08-5 (EC-No.) 227-369-2	0.1 – 1	Flam. Liq. 3, H226 Org. Perox. CD, H242 Acute Tox. 4 (Oral), H302 (ATE=1150 mg/kg bodyweight) Acute Tox. 3 (Inhalation:vapour), H331 (ATE=3.3 mg/l/4h) Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Chronic 2, H411
mequinol; 4-methoxyphenol; hydroquinone monomethyl ether substance with national workplace exposure limit(s) (IE)	(CAS-No.) 150-76-5 (EC-No.) 205-769-8 (EC Index-No.) 604-044-00-7 (REACH-no) 01-2119541813-40	< 0.01	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Eye Irrit. 2, H319 Skin Sens. 1, H317 Repr. 2, H361d Aquatic Chronic 3, H412

Specific concentration limits:			
Name	Product identifier	Specific concentration limits	
$\alpha,\alpha\text{-dimethylbenzyl}$ hydroperoxide; cumene hydroperoxide	(CAS-No.) 80-15-9 (EC-No.) 201-254-7 (EC Index-No.) 617-002-00-8 (REACH-no) 01-2119475796-19	( 0 <c 10)="" 3,="" <="" h335<br="" se="" stot="">( 1 ≤C &lt; 3) Eye Irrit. 2, H319 ( 3 ≤C &lt; 10) Eye Dam. 1, H318 ( 3 ≤C &lt; 10) Skin Irrit. 2, H315 ( 10 ≤C &lt; 100) Skin Corr. 1B, H314</c>	

Note D: Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier must state on the label the name of the substance followed by the words 'non-stabilised'.

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

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

### 4.1. Description of first aid measures

First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Get medical advice/attention if you feel

unwell.

First-aid measures after skin contact : Wash with plenty of soap and water. Wash contaminated clothing before reuse. If skin irritation or rash

occurs: Get medical advice/attention.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing. Get medical advice/attention if you feel unwell.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER/doctor if you feel unwell.

## Maxcem Elite Chroma Catalyst

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

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

Symptoms/effects after inhalation : May cause respiratory irritation.

Symptoms/effects after skin contact May cause an allergic skin reaction. Causes skin irritation.

Symptoms/effects after eye contact : Causes serious eve irritation.

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

Treat symptomatically. In all cases of doubt, or when symptoms persist, seek medical attention.

## **SECTION 5: Firefighting measures**

#### 5.1. Extinguishing media

Suitable extinguishing media Use extinguishing media appropriate for surrounding fire. Foam. Dry powder. Carbon dioxide. Water

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

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

Fire hazard

Explosion hazard Product is not explosive.

Hazardous decomposition products in case of fire Carbon dioxide. Carbon monoxide. Nitrogen oxides. Phosphorus oxides (POx). Halogenated

compounds, metallic oxide.

#### 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 personal protective equipment, including respiratory protection

(EN137).

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

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

: Avoid contact with skin and eyes. Concerning personal protective equipment to use, see section 8. General measures

6.1.1. For non-emergency personnel

Protective equipment : See Section 8.

**Emergency procedures** : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup and emergency crew with proper protection.

**Emergency procedures** Ventilate area.

### 6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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

For containment : Collect all waste in suitable and labelled containers and dispose according to local legislation.

Methods for cleaning up Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage.

Store away from other materials.

#### 6.4. Reference to other sections

For further information refer to section 13. See Section 8. Exposure controls and personal protection.

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

## 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 vapour.

Hygiene measures Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and

when leaving work. Do not eat, drink or smoke when using this product. Wash contaminated clothing

before reuse

## Maxcem Elite Chroma Catalyst

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

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

Storage conditions : Keep container tightly closed. Store in original container. Keep cool. Store in a dry place. Keep container

closed when not in use. Protect from sunlight. Keep away from ignition sources.

: Oxidizing substances. reducing materials. Organic peroxides. Amines.

: Store in a well-ventilated place.

## 7.3. Specific end use(s)

Incompatible materials

No additional data.

Storage area

## SECTION 8: Exposure controls/personal protection

## 8.1. Control parameters

## 8.1.1 National occupational exposure and biological limit values

2,6-Di-tert-butyl-4-methylphenol (BHT) (128-37-0)		
Ireland - Occupational Exposure Limits		
Local name	2,6-Ditertiary-butyl-para-cresol [Butylated hydroxytoluene (BHT)]	
OEL TWA [1]	2 mg/m³	
Regulatory reference	Chemical Agents Code of Practice 2021	
United Kingdom - Occupational Exposure Limits		
Local name	2,6-Di-tert-butyl-p-cresol	
WEL TWA (OEL TWA) [1]	10 mg/m³	
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE	

mequinol; 4-methoxyphenol; hydroquinone monomethyl ether (150-76-5)	
Ireland - Occupational Exposure Limits	
Local name	4-Methoxyphenol [Mequinol]
OEL TWA [1]	5 mg/m³
Regulatory reference	Chemical Agents Code of Practice 2021

phosphorus pentoxide (1314-56-3)		
Gibraltar - Occupational Exposure Limits		
Local name	Diphosphorus pentaoxide	
OEL TWA	1 mg/m³	
Regulatory reference	Factories (Control of Chemical Agents at Work) Regulations 2003 (LN. 2018/181)	
Ireland - Occupational Exposure Limits		
Local name	Diphosphorus pentoxide	
OEL TWA [1]	1 mg/m³	
Remark	IOELV (Indicative Occupational Exposure Limit Values)	
Regulatory reference	Chemical Agents Code of Practice 2021	
Malta - Occupational Exposure Limits		
Local name	Diphosphorus pentaoxide	
OEL TWA	1 mg/m³	
Regulatory reference	S.L.424.24 - Chemical Agents at Work Regulations (L.N.356 of 2021)	
United Kingdom - Occupational Exposure Limits		
Local name	Disphosphorus pentoxide	
WEL TWA (OEL TWA) [1]	1 mg/m³	
WEL STEL (OEL STEL)	2 mg/m³	

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Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (68909-20-6)	
United Kingdom - Occupational Exposure Limits	
Local name	Silica, amorphous
WEL TWA (OEL TWA) [1]	6 mg/m³ inhalable dust 2.4 mg/m³ respirable dust
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

#### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

No additional information available

#### 8.1.5. Control banding

No additional information available

#### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station.

#### 8.2.2. Personal protection equipment

#### Personal protective equipment:

Gloves. Safety glasses.





#### 8.2.2.1. Eye and face protection

#### Eye protection:

Use splash goggles when eye contact due to splashing is possible. STANDARD EN 166.

#### 8.2.2.2. Skin protection

## Skin and body protection:

Wear suitable protective clothing

#### Hand protection:

Wear protective gloves. Butylrubber protective gloves. Layer thickness: 0,2 - 0,4 mm. Breakthrough time: >480 min. STANDARD EN 374.

### 8.2.2.3. Respiratory protection

#### Respiratory protection:

No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation. Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. Extra personal protection: A/P2 filter respirator for organic vapour and harmful dust. STANDARD: EN 140 / EN 141 / EN 136 / EN 143 / EN 405 / EN 137 / EN 147

## 8.2.2.4. Thermal hazards

No additional information available

## 8.2.3. Environmental exposure controls

### Other information:

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke during use. Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment.

Colour

## Maxcem Elite Chroma Catalyst

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Various colours.

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

#### 9.1. Information on basic physical and chemical properties

Physical state : Liquid

Appearance Paste. : mint. Slight. Odour Odour threshold Not determined. Melting point Not determined. Freezing point Not determined Boiling point : Not determined. Flammability : Non flammable.

Explosive properties Oxidising properties : Non flammable. Explosive limits : Not determined. Lower explosive limit (LEL) Not available Upper explosive limit (UEL) Not available Flash point : Not determined. Auto-ignition temperature : Not determined. Decomposition temperature : Not determined. Viscosity, kinematic : Not determined. Viscosity, dynamic Not determined. Solubility Insoluble in water. : Not available

Partition coefficient n-octanol/water (Log Kow) : Not determined. Partition coefficient n-octanol/water (Log Pow) Vapour pressure Not determined. Vapour pressure at 50°C Not available Density : Not available 2.5 g/cm3 Relative density Relative vapour density at 20°C Not determined. Particle size : Not applicable Particle size distribution Not applicable Not applicable Particle shape Particle aspect ratio Not applicable

Particle aggregation state Not applicable Particle agglomeration state Not applicable Particle specific surface area Not applicable Particle dustiness Not applicable

#### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

### 9.2.2. Other safety characteristics

Relative evaporation rate (butylacetate=1) : Not determined.

## **SECTION 10: Stability and reactivity**

#### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

## 10.2. Chemical stability

Stable under normal conditions.

#### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use. No polymerization.

## 10.4. Conditions to avoid

No flames, no sparks. Eliminate all sources of ignition. Direct sunlight. Extremely high or low temperatures.

#### 10.5. Incompatible materials

Oxidizing agent. reducing materials. Organic peroxides. Amines.

#### 10.6. Hazardous decomposition products

No decomposition if stored and used normally

## Maxcem Elite Chroma Catalyst

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

## **SECTION 11: Toxicological information**

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

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

Additional information : Based on available data, the classification criteria are not met

2-hydroxyethyl methacrylate (868-77-9)	
LD50 oral rat	5050 mg/kg
LD50 dermal rabbit	> 3000 mg/kg

2,6-Di-tert-butyl-4-methylphenol (BHT) (128-37-0)	
LD50 oral rat	6000 mg/kg
LD50 dermal rabbit	> 5000 mg/kg

α, α-dimethylbenzyl hydroperoxide; cumene hydroperoxide (80-15-9)	
LD50 oral rat	382 mg/kg

1,1,3,3-Tetramethylbutyl hydroperoxide (5809-08-5)	
LD50 oral rat	1150 mg/kg
LC50 Inhalation - Rat	3.3 mg/l/4h

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (68909-20-6)	
LD50 oral rat	> 5000 mg/kg
LD50 dermal rat	> 3000 mg/kg
LC50 Inhalation - Rat	> 2000 mg/l/4h

L-menthol (2216-51-5)	
LD50 oral rat	3300 mg/kg
LD50 dermal rabbit	> 5000 mg/kg

(R)-p-mentha-1,8-diene; d-limonene (5989-27-5)	
LD50 oral rat	> 5000 mg/kg
LD50 dermal	> 2000 mg/kg

Skin corrosion/irritation : Causes skin irritation.

pH: Not determined.

Serious eye damage/irritation : Causes serious eye irritation.

pH: Not determined.

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

Germ cell mutagenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Carcinogenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-single exposure : May cause respiratory irritation.

2-hydroxy-1,3-propanediyl bismethacrylate (1830-78-0)	
STOT-single exposure	May cause respiratory irritation.

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2,6-Di-tert-butyl-4-methylphenol (BHT) (128-37-0)	
NOAEL (oral, rat)	100 mg/kg bodyweight

STOT-repeated exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

2,6-Di-tert-butyl-4-methylphenol (BHT) (128-37-0)	
NOAEL (oral, rat, 90 days)	25 mg/kg bodyweight/day

α, α-dimethylbenzyl hydroperoxide; cumene hydroperoxide (80-15-9)	
STOT-repeated exposure	May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard : Not classified

Additional information : Based on available data, the classification criteria are not met

Maxcem Elite Chroma Catalyst	
Viscosity, kinematic	Not determined.

#### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties

: The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

11.2.2 Other information

Potential adverse human health effects and symptoms : For further information see section 4

## **SECTION 12: Ecological information**

#### 12.1. Toxicity

Hazardous to the aquatic environment, short–term (acute) : Not classified Hazardous to the aquatic environment, long–term (chronic) : Not classified

2-hydroxyethyl methacrylate (868-77-9)		
LC50 - Fish [1]	227 mg/l (96 hours - Pimephales promelas)	
EC50 - Crustacea [1]	> 280 mg/l Daphnia magna, 48 hours	

2,6-Di-tert-butyl-4-methylphenol (BHT) (128-37-0)			
LC50 - Fish [1] 0.57 g/l (96 hours - Brachydanio rerio, zebra-fish)			
EC50 - Crustacea [1]	0.31 mg/l Daphnia magna, 48 hours		
ErC50 algae	0.42 (96 hours -Scenedesmus subspicatus)		
NOEC chronic crustacea	0.316 mg/l (48 hours -Daphnia hyalina)		

mequinol; 4-methoxyphenol; hydroquinone monomethyl ether (150-76-5)			
LC50 - Fish [1] 28.5 mg/l Oncorhynchus mykiss (Rainbow trout)			
EC50 - Crustacea [1]	3 mg/l Daphnia magna, 48 hours		
ErC50 algae	54.7 mg/l (96 hours - Pseudokirchneriella subcapitata)		
NOEC chronic algae	2.96 mg/l (OECD 201 method)		

α, α-dimethylbenzyl hydroperoxide; cumene hydroperoxide (80-15-9)	
LC50 - Fish [1]	3.9 mg/l (96 hours - Rainbow trout)
EC50 - Crustacea [1]	18 mg/l Daphnia magna, 48 hours

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ErC50 algae	3.1 mg/l 72 hours - Pseudokirchnerella subcapitata			
1,1,3,3-Tetramethylbutyl hydroperoxide (5809-08-5)				
EC50 - Crustacea [1]	6.7 mg/l Daphnia magna, 48 hours			
ErC50 algae	5.6 mg/l			
and the state of t				
L-menthol (2216-51-5)	L-menthol (2216-51-5)			
C50 - Fish [1]         18.9 (96 hours - Pimephales promelas)				
(R)-p-mentha-1,8-diene; d-limonene (5989-27-5)				
LC50 - Fish [1]	0.7 mg/l			
EC50 - Crustacea [1]	0.4 g/l			
12.2. Persistence and degradability				
Maxcem Elite Chroma Catalyst				
Persistence and degradability	Not established.			
2-hydroxyethyl methacrylate (868-77-9)				
Biodegradation	84 % (OECD 301D method)			
	2,6-Di-tert-butyl-4-methylphenol (BHT) (128-37-0)			
Persistence and degradability	Not readily biodegradable.			
Biodegradation 10 % (OECD 301D method)				
mequinol; 4-methoxyphenol; hydroquinone monomethyl e	ther (150-76-5)			
Biodegradation	86 % (OECD 301C method)			
phosphorus pentoxide (1314-56-3)				
Persistence and degradability	Readily biodegradable.			
$\alpha$ , $\alpha$ -dimethylbenzyl hydroperoxide; cumene hydroperoxide	e (80-15-9)			
Biodegradation	18 % (OECD 301C method)			
1,1,3,3-Tetramethylbutyl hydroperoxide (5809-08-5)	Net and the birds and the			
Persistence and degradability	Not readily biodegradable.			
12.3. Bioaccumulative potential				
Maxcem Elite Chroma Catalyst				
Partition coefficient n-octanol/water (Log Pow)	Not determined.			
Bioaccumulative potential	Not established.			
2-hydroxyethyl methacrylate (868-77-9)				
Bioconcentration factor (BCF REACH)	1,3 - 1,5			
Partition coefficient n-octanol/water (Log Pow)	0.47			
2,6-Di-tert-butyl-4-methylphenol (BHT) (128-37-0)				
Bioconcentration factor (BCF REACH)	598			
Partition coefficient n-octanol/water (Log Pow)	5.1			
	·			

## Maxcem Elite Chroma Catalyst

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate (1565-94-2)		
Bioconcentration factor (BCF REACH)	2.46	
Partition coefficient n-octanol/water (Log Pow)	4.94	

α, α-dimethylbenzyl hydroperoxide; cumene hydroperoxide (80-15-9)	
BCF - Fish [1]	2.8
Partition coefficient n-octanol/water (Log Pow)	0.16

L-menthol (2216-51-5)			
Bioconcentration factor (BCF REACH) 15			
Partition coefficient n-octanol/water (Log Pow)	3.3		

#### 12.4. Mobility in soil

Maxcem Elite Chroma Catalyst	
Ecology - soil	Material insoluble in water.

#### 12.5. Results of PBT and vPvB assessment

Maxcem Elite Chroma Catalyst
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

Component			
2,6-Di-tert-butyl-4-methylphenol (BHT) (128-37-0)  This substance/mixture does not meet the PBT criteria of REACH regulation, annex			
	This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII		

## 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

Other adverse effects : None to our knowledge.

Additional information : No other effects known. Avoid release to the environment.

## **SECTION 13: Disposal considerations**

## 13.1. Waste treatment methods

Waste treatment methods : Must not be disposed together with household garbage. Do not allow product to reach the sewage system.

Product/Packaging disposal recommendations : Dis

 $: \ \, \text{Dispose in a safe manner in accordance with local/national regulations. Empty container completely}.$ 

After cleaning, recycle or dispose of at an authorised site.

European List of Waste (LoW) code : 18 01 06\* - chemicals consisting of or containing dangerous substances

## **SECTION 14: Transport information**

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

## Maxcem Elite Chroma Catalyst

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

#### 14.6. Special precautions for user

#### Overland transport

Not applicable

#### Transport by sea

Not applicable

#### Air transport

Not applicable

#### Inland waterway transport

Not applicable

### Rail transport

Not applicable

#### 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

#### 15.1.1. EU-Regulations

Listed on REACH Annex XVII (Restriction Conditions). The following restrictions are applicable:		
Reference code	Applicable on	Entry title or description
40.	1,1,3,3-Tetramethylbutyl hydroperoxide ; (R)-p-mentha-1,8-diene; d-limonene	Substances classified as flammable gases category 1 or 2, flammable liquids categories 1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases, category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids category 1, regardless of whether they appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or not.

Contains no substance(s) listed on the REACH Candidate List

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

#### 15.1.2. National regulations

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/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

## 15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier

## **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/EEC and

1999/45/EC, and amending Regulation (EC) No 1907/2006.

Full text of H- and EUH-statements:

Acute Tox. 3 (Inhalation)

Acute toxicity (inhal.), Category 3

Acute Tox. 3 (Inhalation:vapour)

Acute toxicity (inhalation:vapour) Category 3

Acute Tox. 4 (Dermal)

Acute toxicity (dermal), Category 4

Acute Tox. 4 (Oral)

Acute toxicity (oral), Category 4

Aquatic Acute 1 Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1 Hazardous to the aquatic environment – Chronic Hazard, Category 1
Aquatic Chronic 2 Hazardous to the aquatic environment – Chronic Hazard, Category 2
Aquatic Chronic 3 Hazardous to the aquatic environment – Chronic Hazard, Category 3

 Eye Dam. 1
 Serious eye damage/eye irritation, Category 1

 Eye Irrit. 2
 Serious eye damage/eye irritation, Category 2

STOT RE 2

STOT SE 3

## Maxcem Elite Chroma Catalyst

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Flam. Liq. 3 Flammable liquids, Category 3 H226 Flammable liquid and vapour. H242 Heating may cause a fire. H302 Harmful if swallowed. Harmful in contact with skin. H312 H314 Causes severe skin burns and eye damage. Causes skin irritation H315 H317 May cause an allergic skin reaction. H318 Causes serious eye damage Causes serious eye irritation. H319 Toxic if inhaled. H331 May cause respiratory irritation. H335 Suspected of damaging the unborn child. H361d May cause damage to organs through prolonged or repeated exposure. H373 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 Org. Perox. CD Organic Peroxides, Type C,D Org. Perox. E Organic Peroxides, Type E Repr. 2 Reproductive toxicity, Category 2 Skin Corr. 1A Skin corrosion/irritation, Category 1, Sub-Category 1A Skin Corr. 1B Skin corrosion/irritation, Category 1, Sub-Category 1B Skin Irrit. 2 Skin corrosion/irritation, Category 2 Skin Sens. 1 Skin sensitisation, Category 1

Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation The information in this safety data sheet is based on information from the manufacturer/supplier, present european and national legislation, and presupposes that the product is used within the specified area of application.

Specific target organ toxicity – Repeated exposure, Category 2



according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Issue date: 16/03/2020 Revision date: 09/10/2022 Supersedes version of: 16/03/2020 Version: 1.0

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

#### 1.1. Product identifier

: Mixture Product form Product name SimpliShade

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

#### Relevant identified uses

Main use category : Professional use

: Preparation intended for dental medical use Use of the substance/mixture

Function or use category : Dental materials.

#### Uses advised against

No additional information available

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

Kerr Italia S.r.l. Via Passanti, 174 Scafati (SA) 84018 (Italy)

T +39 081 850 3511 / Information Phone Number: 1-800-841-1428 (Customer Service)

safety@envistaco.com

#### 1.4. Emergency telephone number

Emergency number : CHEMTREC® Emergency Call Center. Emergency Telephone Number (for USA only) 001-800-424-9300

International and Maritime Telephone Number +1 (703) 527-3887

Country	Official advisory body	Address	Emergency number	Comment
Gibraltar	GHA Call Centre Zone 2, Level3, St Bernard's Hospital	Harbour Views Road	+350 200 79700 +350 200 72266	
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
Malta	Medicines & Poisons Info Office	Mater Dei Hospital MSD 2090 Msida	+356 2545 6508	
United Kingdom	National Poisons Information Service (Newcastle Unit)	Claremont Place Newcastle-upon-Tyne, Newcastle	+44 191 2606182 +44 191 2606180	Hours of operation: 24hrs

## **SECTION 2: Hazards identification**

#### 2.1. Classification of the substance or mixture

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

Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT SE 3 H335 Aquatic Chronic 2 H411

Full text of hazard classes and H-statements : see section 16

### Adverse physicochemical, human health and environmental effects

No additional information available

## SimpliShade

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

#### 2.2. Label elements

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

Hazard pictograms (CLP)





GHS07

Signal word (CLP) Warning

Contains 2,2'-ethylenedioxydiethyl dimethacrylate, Poly(oxy-1,2-ethanediyl), α,α'-[(1-methylethylidene)di-4,1-

phenylene]bis[ $\omega$ -[(2-methyl-1-oxo-2-propen-1-yl)oxy]-

Hazard statements (CLP) : H315 - Causes skin irritation.

H319 - Causes serious eye irritation. H335 - May cause respiratory irritation.

H411 - Toxic to aquatic life with long lasting effects. P261 - Avoid breathing vapours, spray, mist. P280 - Wear eye protection, protective gloves.

P304+P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention. P362+P364 - Take off contaminated clothing and wash it before reuse.

P501 - Dispose of contents/container to a hazardous or special waste collection point.

The product is seen as a medical device (Directive 90/385/EEC, 93/42/EEC, 98/79/EC) and therefore not Extra phrases

subject to labelling (EU-regulation 1272/2008, article 1, paragraph 5d).

On basis of test data:

No sensitisation responses were observed.

#### 2.3. Other hazards

Precautionary statements (CLP)

Other hazards which do not result in classification : None under normal conditions. This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

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

## 3.1. Substances

Not applicable

#### 3.2. Mixtures

Name	Product identifier	Conc. (% w/w)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Zirconium dioxide substance with national workplace exposure limit(s) (GB, IE)	(CAS-No.) 1314-23-4 (EC-No.) 215-227-2 (REACH-no) 01-2119486976-14	10 – 60	Not classified
Poly(oxy-1,2-ethanediyl), $\alpha$ , $\alpha$ '-[(1-methylethylidene)di-4,1-phenylene]bis[ $\omega$ -[(2-methyl-1-oxo-2-propen-1-yl)oxy]-	(CAS-No.) 41637-38-1 (EC-No.) 609-946-4 (REACH-no) 01-2119980659-17	5 – 20	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1A, H317 STOT SE 3, H335 Aquatic Chronic 4, H413
silicon dioxide substance with national workplace exposure limit(s) (GB, IE)	(CAS-No.) 7631-86-9 (EC-No.) 231-545-4 (REACH-no) 01-2119379499-16	1 – 10	Not classified
Ytterbium trifluoride substance with national workplace exposure limit(s) (GB, IE); substance with a Community workplace exposure limit	(CAS-No.) 13760-80-0 (EC-No.) 237-354-2 (REACH-no) N/A	≤ 10	Not classified
2,2'-ethylenedioxydiethyl dimethacrylate	(CAS-No.) 109-16-0 (EC-No.) 203-652-6 (REACH-no) 01-2119969287-21	≤ 3	Skin Sens. 1, H317

## SimpliShade

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Oxybenzone	(CAS-No.) 131-57-7 (EC-No.) 205-031-5 (REACH-no) 01-2119976330-39	≤ 1	Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=10)
2,6-di-tert-butyl-p-cresol substance with national workplace exposure limit(s) (GB, IE)	(CAS-No.) 128-37-0 (EC-No.) 204-881-4 (REACH-no) 01-2119480433-40	< 1	Acute Tox. 4 (Oral), H302 (ATE=890 mg/kg bodyweight) Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

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

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

#### 4.1. Description of first aid measures

First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you

feel unwell.

First-aid measures after skin contact : Gently wash with plenty of soap and water. If skin irritation 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

Symptoms/effects after inhalation : May cause respiratory irritation.
Symptoms/effects after skin contact : Causes skin irritation.
Symptoms/effects after eye contact : Causes serious eye irritation.

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

Treat symptomatically. In all cases of doubt, or when symptoms persist, seek medical attention.

## **SECTION 5: Firefighting measures**

## 5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Foam, carbon dioxide (CO2) and powder.

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

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

Fire hazard : Non flammable.

Explosion hazard : Product is not explosive.

Hazardous decomposition products in case of fire : Carbon oxides (CO, CO2). Toxic fumes may be released. Nitrogen oxides. Halogenated compounds.

metallic oxide.

#### 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 personal protective equipment, including respiratory protection

(EN137).

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

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

General measures : Avoid all eye and skin contact and do not breathe vapour and mist. Use personal protective equipment

as required.

6.1.1. For non-emergency personnel

Protective equipment : See Section 8.

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup and emergency crew with proper protection.

## SimpliShade

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Emergency procedures : Ventilate area

#### 6.2. Environmental precautions

Avoid release to the environment. 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

For containment : Collect all waste in suitable and labelled containers and dispose according to local legislation.

Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage.

Store away from other materials.

#### 6.4. Reference to other sections

For further information refer to section 13. See Section 8. Exposure controls and personal protection.

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

#### 7.1. Precautions for safe handling

Precautions for safe handling : Do not eat, drink or smoke when using this product. Wear personal protective equipment. Avoid contact

with skin and eyes. 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 vapour. Avoid breathing vapours. Use only outdoors or in a well-ventilated area.

Hygiene measures : Always wash hands after handling the product. Wash contaminated clothing before reuse. Do not eat,

drink or smoke when using this product.

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

Storage conditions : Keep container tightly closed. Keep only in original container. Keep cool. Protect from sunlight. Store in a

well-ventilated place.

Incompatible materials : Sources of ignition. Direct sunlight.

## 7.3. Specific end use(s)

No additional data.

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

### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

silicon dioxide (7631-86-9)		
Ireland - Occupational Exposure Limits		
Local name	Silica, amorphous	
OEL TWA [1]	2.4 mg/m³	
Regulatory reference	Chemical Agents Code of Practice 2021	
United Kingdom - Occupational Exposure Limits		
Local name	Silica, amorphous : respirable dust	
WEL TWA (OEL TWA) [1]	2.4 mg/m³	
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE	

2,6-di-tert-butyl-p-cresol (128-37-0)		
Ireland - Occupational Exposure Limits		
Local name	2,6-Ditertiary-butyl-para-cresol [Butylated hydroxytoluene (BHT)]	
OEL TWA [1]	2 mg/m³	
Regulatory reference	Chemical Agents Code of Practice 2021	
United Kingdom - Occupational Exposure Limits		
Local name	2,6-Di-tert-butyl-p-cresol	
WEL TWA (OEL TWA) [1]	10 mg/m³	
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE	

## SimpliShade

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Ytterbium trifluoride (13760-80-0)		
Ireland - Occupational Exposure Limits		
Local name	Fluoride (as F)	
OEL TWA [1]	2.5 mg/m³	
United Kingdom - Occupational Exposure Limits		
Local name	Fluoride	
WEL TWA (OEL TWA) [1]	2.5 mg/m³ (inorganic as F)	

Zirconium dioxide (1314-23-4)		
Ireland - Occupational Exposure Limits		
Local name	Zirconium compounds (as Zr)	
OEL TWA [1]	5 mg/m³	
OEL STEL	10 mg/m³	
Regulatory reference	Chemical Agents Code of Practice 2021	
United Kingdom - Occupational Exposure Limits		
Local name	Zirconium	
WEL TWA (OEL TWA) [1]	5 mg/m³ compounds (as Zr)	
WEL STEL (OEL STEL)	10 mg/m³ compounds (as Zr)	
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE	

#### 8.1.2. Recommended monitoring procedures

No additional information available

## 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

No additional information available

## 8.1.5. Control banding

No additional information available

## 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

### Appropriate engineering controls:

Ensure good ventilation of the work station.

#### 8.2.2. Personal protection equipment

## Personal protective equipment:

Gloves. Safety glasses.





#### 8.2.2.1. Eye and face protection

### Eye protection:

Use splash goggles when eye contact due to splashing is possible. STANDARD EN 166:2001

#### 8.2.2.2. Skin protection

## Skin and body protection:

Wear suitable protective clothing

## SimpliShade

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

#### Hand protection:

Wear protective gloves. Nitrile rubber gloves. Breakthrough time: 6 (> 480 minutes). Layer thickness: 0,2 - 0,4 mm. STANDARD EN ISO 374-1:2016/A1:2018, EN ISO 374-2:2019, EN ISO 374-4:2019

#### 8.2.2.3. Respiratory protection

#### Respiratory protection:

No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation

#### 8.2.2.4. Thermal hazards

No additional information available

#### 8.2.3. Environmental exposure controls

#### Other information:

Do not eat, drink or smoke during use. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment.

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

#### 9.1. Information on basic physical and chemical properties

Physical state Colour Various colours. Appearance Paste. Fruity. Ester. Odour Odour threshold Not determined. Melting point : Not determined. Freezing point : Not determined. Boiling point Flammability : Non flammable. Explosive properties Product is not explosive.

Oxidising properties Non flammable. Explosive limits Not available Lower explosive limit (LEL) Not available Upper explosive limit (UEL) : Not available Flash point Not determined. Auto-ignition temperature Not determined Decomposition temperature Not determined. Not determined. pН Viscosity, kinematic Not determined. Viscosity, dynamic : Not determined. Solubility : Insoluble in water. Partition coefficient n-octanol/water (Log Kow) Not available : Not determined. Partition coefficient n-octanol/water (Log Pow) Vapour pressure : Not determined. Vapour pressure at 50 °C Not determined. Density Not available

Relative vapour density at 20 °C Not determined. Not applicable Particle size Particle size distribution Not applicable Particle shape Not applicable Not applicable Particle aspect ratio Not applicable Particle aggregation state Particle agglomeration state Not applicable Particle specific surface area Not applicable Not applicable Particle dustiness

: 1.97

### 9.2. Other information

Relative density

## 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

Relative evaporation rate (butylacetate=1) : Not determined.

## SimpliShade

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

## **SECTION 10: Stability and reactivity**

#### 10.1. Reactivity

None to our knowledge.

#### 10.2. Chemical stability

Stable under normal conditions of use.

#### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

#### 10.4. Conditions to avoid

None to our knowledge.

#### 10.5. Incompatible materials

Oxidizing materials. reducing materials. Amines. Organic peroxides.

#### 10.6. Hazardous decomposition products

No decomposition if stored and used normally.

## **SECTION 11: Toxicological information**

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

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

Additional information : Based on available data, the classification criteria are not met

2,2'-ethylenedioxydiethyl dimethacrylate (109-16-0)	
LD50 oral rat	10837 mg/kg

Oxybenzone (131-57-7)	
LD50 oral rat	7400 mg/kg
LD50 dermal rabbit	> 16 g/kg

silicon dioxide (7631-86-9)	
LD50 oral rat	> 15000 mg/kg
LD50 dermal rabbit	> 2000 mg/kg

2,6-di-tert-butyl-p-cresol (128-37-0)	
LD50 oral rat	890 mg/kg

Zirconium dioxide (1314-23-4)	
LD50 oral rat	> 8800 mg/kg

LD50 oral rat	> 8800 mg/kg
Skin corrosion/irritation :	Causes skin irritation.

		pH: Not determined.
Serious eye damage/irritation	:	Causes serious eye irritation.
		pH: Not determined.
Respiratory or skin sensitisation	:	Not classified

Additional information : Based on available data, the classification criteria are not met Germ cell mutagenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Carcinogenicity : Not classified
Additional information : Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified

Additional information : Based on available data, the classification criteria are not met

## SimpliShade

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

STOT-single exposure : May cause respiratory irritation.

$Poly(oxy-1,2-ethanediyl),\ \alpha,\alpha'-[(1-methylethylidene)di-4,1-phenylene]bis[\omega-[(2-methyl-1-oxo-2-propen-1-yl)oxy]-\ (41637-38-1)$	
STOT-single exposure	May cause respiratory irritation.

2,6-di-tert-butyl-p-cresol (128-37-0)	
STOT-single exposure	May cause respiratory irritation.

STOT-repeated exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

Aspiration hazard : Not classified

Additional information : Based on available data, the classification criteria are not met

SimpliShade	
Viscosity, kinematic	Not determined.

#### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting

properties

: The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

11.2.2 Other information

Potential adverse human health effects and symptoms : For further information see section 4

## **SECTION 12: Ecological information**

## 12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified

Hazardous to the aquatic environment, long-term (chronic) : Toxic to aquatic life with long lasting effects.

Oxybenzone (131-57-7)	
ErC50 algae	0.01387 mg/l

silicon dioxide (7631-86-9)	
LC50 - Fish [1]	5000 mg/l (96 hours - Brachydanio rerio, zebra-fish)
EC50 - Crustacea [1]	7600 mg/l (48 hours - Ceriodaphnia dubia)
ErC50 algae	440 mg/l (EC50, 72 hours - Selenastrum capricornutum)

2,6-di-tert-butyl-p-cresol (128-37-0)	
LC50 - Fish [1]	> 0.57 mg/l
EC50 - Crustacea [1]	0.42 mg/l (48 hours - Daphnia magna)
ErC50 algae	0.31 mg/l

#### 12.2. Persistence and degradability

SimpliShade	
Persistence and degradability	May cause long-term adverse effects in the environment.

2,6-di-tert-butyl-p-cresol (128-37-0)	
Persistence and degradability	Not readily biodegradable.
Biodegradation	10 % (OECD 301D method)

## SimpliShade

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

## 12.3. Bioaccumulative potential

SimpliShade	
Partition coefficient n-octanol/water (Log Pow)  Not determined.	
Bioaccumulative potential	No data.

Oxybenzone (131-57-7)	
Bioconcentration factor (BCF REACH)	39-160
Partition coefficient n-octanol/water (Log Pow)	3.79

2,6-di-tert-butyl-p-cresol (128-37-0)	
Bioconcentration factor (BCF REACH) 330-1800	
Partition coefficient n-octanol/water (Log Pow)	3.79
Bioaccumulative potential	Potentially bioaccumulable.

#### 12.4. Mobility in soil

SimpliShade	
Ecology - soil	No data.

#### 12.5. Results of PBT and vPvB assessment

SimpliShade
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

### 12.6. Endocrine disrupting properties

No additional information available

#### 12.7. Other adverse effects

Other adverse effects : None to our knowledge.

Additional information : No other effects known. Avoid release to the environment.

## **SECTION 13: Disposal considerations**

#### 13.1. Waste treatment methods

Waste treatment methods : Must not be disposed together with household garbage. Do not allow product to reach the sewage

system.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Empty container completely.

After cleaning, recycle or dispose of at an authorised site.

European List of Waste (LoW) code : 18 01 06\* - chemicals consisting of or containing dangerous substances

## **SECTION 14: Transport information**

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

In accordance with ADIV / IMDG / IATA / ADIV / IND /				
ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
UN 3082	UN 3082	UN 3082	UN 3082	UN 3082
14.2. UN proper shipping name				
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxybenzone; 2,6-di-tert-butyl-p-cresol)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxybenzone; 2,6-di-tert-butyl-p-cresol)	Environmentally hazardous substance, liquid, n.o.s. (Oxybenzone ; 2,6-di-tert-butyl- p-cresol)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxybenzone; 2,6-di-tert-butyl-p-cresol)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxybenzone; 2,6-di-tert-butyl-p-cresol)

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Transport document description	on				
UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxybenzone; 2,6-di-tert-butyl-p-cresol), 9, III, (-)	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxybenzone; 2,6-di-tert-butyl-p-cresol), 9, III, MARINE POLLUTANT	UN 3082 Environmentally hazardous substance, liquid, n.o.s. (Oxybenzone ; 2,6-di-tert- butyl-p-cresol), 9, III	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxybenzone; 2,6-di-tert-butyl-p-cresol), 9, III	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxybenzone; 2,6-di-tert-butyl-p-cresol), 9, III	
14.3. Transport hazard class(e	s)				
9	9	9	9	9	
	**************************************				
14.4. Packing group	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 av	/ailable		1		

#### 14.6. Special precautions for user

### Overland transport

Classification code (ADR) : M6

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

Limited quantities (ADR) : 5I

Excepted quantities (ADR) : E1

Orange plates :

90 3082

EAC code : •3Z

Transport by sea

Special provisions (IMDG) : 274, 335, 969

 Limited quantities (IMDG)
 : 5 L

 Excepted quantities (IMDG)
 : E1

 EmS-No. (Fire)
 : F-A

 EmS-No. (Spillage)
 : S-F

Air transport

PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y964

Special provisions (IATA) : A97, A158, A197

Inland waterway transport

Classification code (ADN) : M6

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

Limited quantities (ADN) : 5 L
Excepted quantities (ADN) : E1

Rail transport

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

 Limited quantities (RID)
 : 5L

 Excepted quantities (RID)
 : E1

 Hazard identification number (RID)
 : 90

## 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

## **SECTION 15: Regulatory information**

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

#### 15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

#### 15.1.2. National regulations

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/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## **SECTION 16: Other information**

Indication of changes:			
Section	Changed item	Change	Comments
2.2	Precautionary statements (CLP)	Modified	
8.2	Personal protective equipment	Added	

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on

 $classification, labelling \ and \ packaging \ of \ substances \ and \ mixtures, \ amending \ and \ repealing \ Directives \ 67/548/EEC \ and$ 

1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

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

Acute Tox. 4 (Oral) Acute toxicity (oral), Category 4

Aquatic Acute 1 Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1 Hazardous to the aquatic environment – Chronic Hazard, Category 1
Aquatic Chronic 2 Hazardous to the aquatic environment – Chronic Hazard, Category 2
Aquatic Chronic 4 Hazardous to the aquatic environment – Chronic Hazard, Category 4

Eye Irrit. 2 Serious eye damage/eye irritation, Category 2

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
 H410 Very toxic to aquatic life with long lasting effects.
 H411 Toxic to aquatic life with long lasting effects.
 H413 May cause long lasting harmful effects to aquatic life.

Skin Irrit. 2 Skin corrosion/irritation, Category 2
Skin Sens. 1 Skin sensitisation, Category 1
Skin Sens. 1A Skin sensitisation, category 1A

STOT SE 3 Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

The information in this safety data sheet is based on information from the manufacturer/supplier, present european and national legislation, and presupposes that the product is used within the specified area of application.



according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Issue date: 02/03/2018 Revision date: 21/09/2022 Supersedes version of: 22/05/2018 Version: 2.0

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

#### 1.1. Product identifier

Product form Mixture

Product name OptiBond Universal

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

#### Relevant identified uses

Main use category : Professional use Use of the substance/mixture : Dental Adhesive

Use of the substance/mixture Preparation intended for dental medical use

Function or use category : Dental materials.

#### Uses advised against

No additional information available

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

#### Supplier

Kerr Italia S.r.l. Via Passanti, 174 Scafati (SA) 84018 (Italy)

T +39 081 850 3511 / Information Phone Number: 1-800-841-1428 (Customer Service)

safety@envistaco.com

United Kingdom

#### 1.4. Emergency telephone number

: CHEMTREC® Emergency Call Center. Emergency Telephone Number (for USA only) 001-800-424-9300 **Emergency number** International and Maritime Telephone Number +1 (703) 527-3887

Country Official advisory body Comment **Emergency number** Harbour Views Road Gibraltar +350 200 79700 **GHA Call Centre** Zone 2. Level3. St Bernard's Hospital +350 200 72266 PO Box 1297 +353 1 809 2566 (Healthcare Ireland National Poisons Information Centre Beaumont Hospital Beaumont Road professionals-24/7) 9 Dublin +353 1 809 2166 (public, 8am - 10pm, 7/7) +356 2545 6508 Malta Medicines & Poisons Info Office Mater Dei Hospital MSD 2090 Msida

Claremont Place

Newcastle-upon-Tyne, Newcastle

+44 191 2606182

+44 191 2606180

## **SECTION 2: Hazards identification**

#### 2.1. Classification of the substance or mixture

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

(Newcastle Unit)

Flam. Liq. 2 H225 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1 H317 STOT SE 3 H335 STOT SE 3 H336

National Poisons Information Service

Full text of hazard classes and H-statements : see section 16

### Adverse physicochemical, human health and environmental effects

No additional information available

Hours of operation: 24hrs

## OptiBond Universal

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

#### 2.2. Label elements

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

Hazard pictograms (CLP)





GHS02

2 GHS

Signal word (CLP) : Danger

Contains : 2-hydroxyethyl methacrylate, 2-hydroxy-1,3-propanediyl bismethacrylate, Glycerol Phosphate

Dimethacrylate, acetone; propan-2-one; propanone

Hazard statements (CLP) : H225 - Highly flammable liquid and vapour.

H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction. H319 - Causes serious eye irritation. H335 - May cause respiratory irritation. H336 - May cause drowsiness or dizziness.

Precautionary statements (CLP) : P210 - Keep away from heat, hot surfaces, open flames, sparks. – No smoking.

P233 - Keep container tightly closed.
P261 - Avoid breathing mist, spray, vapours.
P280 - Wear eye protection, protective gloves.

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

lenses, if present and easy to do. Continue rinsing.

P337+P313 - If eye irritation persists: Get medical advice/attention.

P403+P235 - Store in a well-ventilated place. Keep cool.

P303+P361+P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse

skin with water/shower.

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

Extra phrases : The product is seen as a medical device (Directive 90/385/EEC, 93/42/EEC, 98/79/EC) and therefore not

subject to labelling (EU-regulation 1272/2008, article 1, paragraph 5d).

A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety

Information Sheet has been created on a voluntary basis.

For professional users only.

#### 2.3. Other hazards

Other hazards which do not result in classification : None under normal conditions. This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

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

## 3.1. Substances

Not applicable

#### 3.2. Mixtures

Name	Product identifier	Conc. (% w/w)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
acetone; propan-2-one; propanone substance with national workplace exposure limit(s) (GB, GI, IE, MT); substance with a Community workplace exposure limit	(CAS-No.) 67-64-1 (EC-No.) 200-662-2 (EC Index-No.) 606-001-00-8	30 – 60	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
2-hydroxyethyl methacrylate (Note D)	(CAS-No.) 868-77-9 (EC-No.) 212-782-2 (EC Index-No.) 607-124-00-X (REACH-no) 01-2119490169-29	1 – 10	Eye Irrit. 2, H319 Skin Irrit. 2, H315 Skin Sens. 1, H317
2-hydroxy-1,3-propanediyl bismethacrylate	(CAS-No.) 1830-78-0 (EC-No.) 217-388-4 (REACH-no) N/A	1 – 10	Eye Irrit. 2, H319 Skin Irrit. 2, H315 STOT SE 3, H335

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Glycerol Phosphate Dimethacrylate	(CAS-No.) N/A (EC-No.) N/A	1 – 10	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
Ethanol; ethyl alcohol substance with national workplace exposure limit(s) (GB)	(CAS-No.) 64-17-5 (EC-No.) 200-578-6 (EC Index-No.) 603-002-00-5	1 – 10	Flam. Liq. 2, H225

Note D: Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier must state on the label the name of the substance followed by the words 'non-stabilised'.

Full text of H- and EUH-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

First-aid measures after inhalation Move to fresh air. If breathing is difficult have qualified personnel administer oxygen. If breathing has

the label where possible).

stopped, administer artificial respiration. Get medical attention if breathing is difficult or symptoms of

First-aid measures after skin contact : Immediately flush skin with water for several minutes while removing contaminated clothing. Wash with

soap and water Get medical attention if irritation or rash develops. Launder contaminated clothing before

: Flush eyes with water for 15 minutes. Remove contact lenses, if present, after the first 5 minutes, then First-aid measures after eye contact

continue rinsing. Get medical attention if irritation persists.

If conscious, rinse mouth with water. Do not induce vomiting unless directed by medical personnel. Never First-aid measures after ingestion

give anything by mouth to an unconscious person. Get medical attention.

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

Symptoms/effects after inhalation May cause respiratory irritation. May cause drowsiness or dizziness.

Symptoms/effects after skin contact May cause an allergic skin reaction. Causes skin irritation. Repeated exposure may cause skin dryness

or cracking

Symptoms/effects after eye contact : Causes serious eye irritation.

: Ingestion may cause gastrointestinal irritation, nausea and vomiting. Symptoms/effects after ingestion

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

Treat symptomatically. In all cases of doubt, or when symptoms persist, seek medical attention.

## **SECTION 5: Firefighting measures**

### 5.1. Extinguishing media

Suitable extinguishing media : Dry powder, Carbon dioxide, Water spray, alcohol resistant foam, Use water spray or fog for cooling

exposed containers.

Unsuitable extinguishing media Do not use a heavy water stream.

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

Fire hazard : Highly flammable liquid and vapour. The vapours are denser than air and may travel along the ground.

Distance ignition possible. Under fire conditions closed containers may rupture or explode.

Explosion hazard May form flammable/explosive vapour-air mixture.

Hazardous decomposition products in case of fire : Carbon dioxide. Carbon monoxide. Phosphorus oxides (POx).

## 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 personal protective equipment, including respiratory protection

(EN137).

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

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

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

: Avoid all eye and skin contact and do not breathe vapour and mist. Use personal protective equipment General measures

as required. Concerning personal protective equipment to use, see section 8. Eliminate every possible

source of ignition. Provide good ventilation in process area to prevent formation of flammable vapour.

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment Equip cleanup and emergency crew with proper protection.

**Emergency procedures** Ventilate area.

#### 6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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

: Collect all waste in suitable and labelled containers and dispose according to local legislation. For containment

: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Methods for cleaning up

Store away from other materials. Use only non-sparking tools.

#### 6.4. Reference to other sections

For further information refer to section 13. See Section 8. Exposure controls and personal protection.

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

#### 7.1. Precautions for safe handling

Additional hazards when processed : Handle empty containers with care because residual vapours are flammable. Precautions for safe handling

Avoid contact with skin, eyes and clothing. Wear appropriate personal protective equipment - see Section 8. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use only non-sparking tools. Ground/bond container and receiving equipment.

Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing

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

Storage conditions : Keep container tightly closed. Store in original container. Keep cool. Store in a dry place. Keep container

closed when not in use. Keep in fireproof place. Store in accordance with regulations for the storage of flammable liquids. Store in a cool, dry, well-ventilated area away from heat, direct sunlight and all

sources of ignition. Store away from oxidizers and other incompatible materials.

Storage area : Store in a well-ventilated place.

### 7.3. Specific end use(s)

No additional data.

Hygiene measures

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

### 8.1. Control parameters

## 8.1.1 National occupational exposure and biological limit values

Ethanol; ethyl alcohol (64-17-5)	
United Kingdom - Occupational Exposure Limits	
Local name	Ethanol
WEL TWA (OEL TWA) [1]	1920 mg/m³
WEL TWA (OEL TWA) [2]	1000 ppm
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

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acetone; propan-2-one; propanone (67-64-1)		
Gibraltar - Occupational Exposure Limits		
Local name	Acetone	
OEL TWA	1210 mg/m³	
OEL TWA [ppm]	500 ppm	
Regulatory reference	Factories (Control of Chemical Agents at Work) Regulations 2003 (LN. 2018/181)	
Ireland - Occupational Exposure Limits		
Local name	Acetone	
OEL TWA [1]	1210 mg/m³	
OEL TWA [2]	500 ppm	
Remark	IOELV (Indicative Occupational Exposure Limit Values)	
Regulatory reference	Chemical Agents Code of Practice 2021	
Malta - Occupational Exposure Limits		
Local name	Acetone	
OEL TWA	1210 mg/m³	
OEL TWA [ppm]	500 ppm	
Regulatory reference	S.L.424.24 - Chemical Agents at Work Regulations (L.N.356 of 2021)	
United Kingdom - Occupational Exposure Limits		
Local name	Acetone	
WEL TWA (OEL TWA) [1]	1210 mg/m³	
WEL TWA (OEL TWA) [2]	500 ppm	
WEL STEL (OEL STEL)	3620 mg/m³	
WEL STEL (OEL STEL) [ppm]	1500 ppm	
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE	

#### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

## 8.1.4. DNEL and PNEC

No additional information available

## 8.1.5. Control banding

No additional information available

#### 8.2. Exposure controls

## 8.2.1. Appropriate engineering controls

## Appropriate engineering controls:

Ensure good ventilation of the work station.

## 8.2.2. Personal protection equipment

## Personal protective equipment:

Gloves. Safety glasses.





#### 8.2.2.1. Eye and face protection

## Eye protection:

Chemical goggles or safety glasses. STANDARD EN 166.

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#### 8.2.2.2. Skin protection

#### Skin and body protection:

Wear suitable protective clothing

#### Hand protection:

Wear protective gloves. Butylrubber protective gloves. Layer thickness: 0,2 - 0,4 mm. Breakthrough time: >480 min. STANDARD EN 374.

#### 8.2.2.3. Respiratory protection

#### Respiratory protection:

Not required. Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. Use respiratory equipment with combination filter, type AX/P2. STANDARD: EN 140 / EN 141 / EN 136 / EN 143 / EN 405 / EN 137 / EN 147

#### 8.2.2.4. Thermal hazards

No additional information available

#### 8.2.3. Environmental exposure controls

#### Other information:

Do not eat, drink or smoke during use. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment.

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

#### 9.1. Information on basic physical and chemical properties

Physical state: LiquidColour: Light yellow.Odour: Fruity.

Odour threshold : 4.58 ppm (acetone)
Melting point : Not determined.
Freezing point : Not determined.

Boiling point : 58.08 °C (133°F) (acetone)
Flammability : Highly flammable liquid and vapour.

Explosive properties : Product is not explosive.

Oxidising properties : Highly flammable liquid and vapour.

Decomposition temperature : Not available pH : Not available Viscosity, kinematic : Not available Viscosity, dynamic : Not available : Not available

Solubility : In water, material is partially soluble.

Not applicable

: Not available Partition coefficient n-octanol/water (Log Kow) Partition coefficient n-octanol/water (Log Pow) : Not determined. Vapour pressure : Not determined. Vapour pressure at 50 °C Not available : Not available Density Relative density Not available Relative vapour density at 20 °C Not available Particle size Not applicable Particle size distribution Not applicable Not applicable Particle shape Particle aspect ratio Not applicable Particle aggregation state Not applicable Particle agglomeration state Not applicable Particle specific surface area Not applicable

## 9.2. Other information

Particle dustiness

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

## 9.2.2. Other safety characteristics

Relative evaporation rate (butylacetate=1) : Not available

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VOC content : 460 g/l

## **SECTION 10: Stability and reactivity**

#### 10.1. Reactivity

Loss of inhibitor may allow the product to polymerize.

#### 10.2. Chemical stability

Stable.

## 10.3. Possibility of hazardous reactions

Excessive heat and ultraviolet light may allow the product to polymerize.

#### 10.4. Conditions to avoid

Highly flammable liquid and vapour. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

#### 10.5. Incompatible materials

Oxidizing materials. reducing materials. alkalis. Amines. Sulfur compounds. Organic peroxides. Free radical initiators. inert gas. oxygen scavengers.

#### 10.6. Hazardous decomposition products

Thermal decomposition generates: Carbon dioxide. Carbon monoxide. Phosphorus oxides (POx).

## **SECTION 11: Toxicological information**

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

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

Additional information : Based on available data, the classification criteria are not met

2-hydroxyethyl methacrylate (868-77-9)	
LD50 oral rat	5050 mg/kg
LD50 dermal rabbit	> 3000 mg/kg

Ethanol; ethyl alcohol (64-17-5)	
LD50 oral rat	7060 mg/kg
LD50 dermal rabbit	> 20000 mg/m³
LC50 Inhalation - Rat (Vapours)	124.7 mg/l/4h

acetone; propan-2-one; propanone (67-64-1)	
LD50 oral rat	5800 mg/kg
LD50 dermal rabbit	> 15688 mg/kg
LC50 Inhalation - Rat	76 mg/l
LC50 Inhalation - Rat (Vapours)	76 mg/l/4h

Skin corrosion/irritation : Causes skin irritation.
pH: Not available

: Prolonged or repeated contact may cause skin to become dry or cracked

Additional information : Prolonged or repeated contact Serious eye damage/irritation : Causes serious eye irritation.

pH: Not available

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

Germ cell mutagenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Carcinogenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified

Additional information : Based on available data, the classification criteria are not met

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STOT-single exposure : May cause respiratory irritation. May cause drowsiness or dizziness.

2-hydroxy-1,3-propanediyl bismethacrylate (1830-78-0)	
STOT-single exposure	May cause respiratory irritation.

Glycerol Phosphate Dimethacrylate (N/A)	
STOT-single exposure	May cause respiratory irritation.

acetone; propan-2-one; propanone (67-64-1)	
STOT-single exposure	May cause drowsiness or dizziness.

STOT-repeated exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

Aspiration hazard : Not classified

Additional information : Based on available data, the classification criteria are not met

OptiBond Universal	
Viscosity, kinematic	Not available

#### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

11.2.2 Other information

Potential adverse human health effects and symptoms : For further information see section 4

## **SECTION 12: Ecological information**

### 12.1. Toxicity

Hazardous to the aquatic environment, short–term (acute) : Not classified Hazardous to the aquatic environment, long–term (chronic) : Not classified

2-hydroxyethyl methacrylate (868-77-9)	
LC50 - Fish [1]	227 mg/l (96 hours - Pimephales promelas)
EC50 - Crustacea [1]	> 280 mg/l Daphnia magna, 48 hours

Ethanol; ethyl alcohol (64-17-5)	
LC50 - Fish [1]	13500 mg/l (96 hours - Pimephales promelas)
EC50 - Crustacea [1]	54000 mg/l (48 hours - Daphnia magna)

acetone; propan-2-one; propanone (67-64-1)	
LC50 - Fish [1]	5540 mg/l Oncorhynchus mykiss (Rainbow trout)
EC50 - Crustacea [1]	13500 mg/l (48 hours - Daphnia magna)
ErC50 algae	11493 mg/l
NOEC (chronic)	1000 mg/l

#### 12.2. Persistence and degradability

OptiBond Universal	
Persistence and degradability	Not established.

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

2-hydroxyethyl methacrylate (868-77-9)	
Biodegradation	84 % (OECD 301D method)

Ethanol; ethyl alcohol (64-17-5)		
BOD (% of ThOD)	≥ 0.4 % ThOD BOD5/COD	
Biodegradation	85 % (OECD 301D method)	

acetone; propan-2-one; propanone (67-64-1)		
Persistence and degradability	Biodegradable.	
BOD (% of ThOD)	0.96 % ThOD BOD5/COD	
Biodegradation	< 78 % (OECD 301D method)	

#### 12.3. Bioaccumulative potential

OptiBond Universal		
Partition coefficient n-octanol/water (Log Pow)	Not determined.	
Bioaccumulative potential	Bioaccumulation unlikely.	

2-hydroxyethyl methacrylate (868-77-9)		
Bioconcentration factor (BCF REACH)	1,3 - 1,5	
Partition coefficient n-octanol/water (Log Pow)	0.47	

acetone; propan-2-one; propanone (67-64-1)	
Bioconcentration factor (BCF REACH)	0.65
Partition coefficient n-octanol/water (Log Pow)	-0.27

## 12.4. Mobility in soil

OptiBond Universal	
Ecology - soil	Acetone and ethanol are highly mobile in soil.

## 12.5. Results of PBT and vPvB assessment

## OptiBond Universal

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

## 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

Other adverse effects : None to our knowledge.

Additional information : Avoid release to the environment.

## **SECTION 13: Disposal considerations**

#### 13.1. Waste treatment methods

Waste treatment methods : Must not be disposed together with household garbage. Do not allow product to reach the sewage

system.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Empty container completely.

After cleaning, recycle or dispose of at an authorised site.

European List of Waste (LoW) code : 08 04 09\* - waste adhesives and sealants containing organic solvents or other dangerous substances

20 01 27\* - paint, inks, adhesives and resins containing dangerous substances

## **OptiBond Universal**

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

## **SECTION 14: Transport information**

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
UN 1133	UN 1133	UN 1133	UN 1133	UN 1133
14.2. UN proper shipping name	<b>)</b>			
ADHESIVES (acetone, propan- 2-one, propanone ; ethanol, ethyl alcohol)	ADHESIVES (acetone, propan- 2-one, propanone ; ethanol, ethyl alcohol)	Adhesives (acetone, propan-2- one, propanone ; ethanol, ethyl alcohol)	ADHESIVES (acetone, propan- 2-one, propanone ; ethanol, ethyl alcohol)	ADHESIVES (acetone, propan- 2-one, propanone ; ethanol, ethyl alcohol)
Transport document description	on			
UN 1133 ADHESIVES (acetone, propan-2-one, propanone ; ethanol, ethyl alcohol), 3, II, (D/E)	UN 1133 ADHESIVES (acetone, propan-2-one, propanone ; ethanol, ethyl alcohol), 3, II	UN 1133 Adhesives (acetone, propan-2-one, propanone; ethanol, ethyl alcohol), 3, II	UN 1133 ADHESIVES (acetone, propan-2-one, propanone ; ethanol, ethyl alcohol), 3, II	UN 1133 ADHESIVES (acetone, propan-2-one, propanone ; ethanol, ethyl alcohol), 3, II
14.3. Transport hazard class(es	<u> </u> s)			
3	3	3	3	3
3	3	3	3	3
14.4. Packing group	14.4. Packing group			
II	II	II	II	II
14.5. Environmental hazards				
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information av	No supplementary information available			

#### 14.6. Special precautions for user

Overland transport

 Classification code (ADR)
 : F1

 Special provisions (ADR)
 : 640D

 Limited quantities (ADR)
 : 5I

 Excepted quantities (ADR)
 : E2

Excepted quantities (ADR) :
Orange plates :

33 1133

EAC code : •3YE

Transport by sea

 Limited quantities (IMDG)
 : 5 L

 Excepted quantities (IMDG)
 : E2

 EmS-No. (Fire)
 : F-E

 EmS-No. (Spillage)
 : S-D

Air transport

PCA Excepted quantities (IATA) : E2
PCA Limited quantities (IATA) : Y341
Special provisions (IATA) : A3

Inland waterway transport

Classification code (ADN) : F1
Special provisions (ADN) : 640D
Limited quantities (ADN) : 5 L
Excepted quantities (ADN) : E2

Rail transport

Special provisions (RID) : 640D Excepted quantities (RID) : E2

## OptiBond Universal

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Hazard identification number (RID) : 33

#### 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

#### 15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

VOC content : 460 g/l

#### 15.1.2. National regulations

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/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier

## **SECTION 16: Other information**

Indication of changes:			
Section	Changed item	Change	Comments
2.2	Precautionary statements (CLP)	Modified	
8.2	Personal protective equipment	Modified	

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/EEC and

1999/45/EC, and amending Regulation (EC) No 1907/2006.

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

Eye Irrit. 2 Serious eye damage/eye irritation, Category 2

Flam. Liq. 2 Flammable liquids, Category 2 H225 Highly flammable liquid and vapour H315 Causes skin irritation H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H336 May cause drowsiness or dizziness Skin Irrit. 2 Skin corrosion/irritation, Category 2

Skin Sens. 1 Skin sensitisation, Category 1

STOT SE 3 Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

The information in this safety data sheet is based on information from the manufacturer/supplier, present european and national legislation, and presupposes that the product is used within the specified area of application.