Safety Data Sheet

according to Regulation (EC) No. 453/2010

Revision date: 09/07/2014 Date of issue: 09/07/2014

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

1.1. Product Identifier

Product form : Mixture

Product Name : DE Healthcare Temporary Cement Zincoxide Eugenol base, 45g, REF 9796643

Synonyms : ZOE Eugenol Temporary Cement B

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional dental use only.
Use of the substance/mixture : For temporary restorative treatment.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

DE Healthcare Ltd., Unit 9, Kingsthorpe Business Centre, Studland Road, Kingsthorpe, Northampton NN2 6NE U.K. **Tel.:** +44 1634 266 056 **E-Mail:** info@dehpbrand.com

1.4. Emergency Telephone Number

Emergency #: Chemtrec US (800) 424-9300 EU Tel.: 112 International: 001 703-527-3887 Suisse: 145

SECTION 2: Hazards identification

2.1. Classification of the Substance or Mixture

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

Eye Irrit. 2 H319 Aquatic Acute 1 H400 Aquatic Chronic 1 H410

Full text of H-phrases: see section 16

Classification according to Directive 67/548/EEC or 1999/45/EC

Xi; R36 N; R50/53

Full text of R-phrases: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label Elements

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

Hazard pictograms (CLP)





GHS07

Signal word (CLP) : Warning

Hazard statements (CLP) : H319 - Causes serious eye irritation

H410 - Very toxic to aquatic life with long lasting effects

Precautionary statements (CLP) : P264 - Wash hands, forearms, and exposed areas thoroughly after handling.

P273 - Avoid release to the environment.

P280 - Wear eye protection, protective clothing, 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.

09/07/2014 EN (English) 1/8

Version: 1.0

Safety Data Sheet

according to Regulation (EC) No. 453/2010

P391 - Collect spillage.

P501 - Dispose of contents/container according to local, regional, national, and international regulations.

2.3. Other Hazards

Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	Classification according to Directive 67/548/EEC
Zinc oxide	(CAS No) 1314-13-2 (EC no) 215-222-5 (EC index no) 030-013-00-7	70 - 90	N; R50/53
Castor oil	(CAS No) 8001-79-4 (EC no) 232-293-8	10 - 20	Xi; R36
Glycerin substance with national workplace exposure limit(s) (BE, CZ, ES, ET, FI, FR, GB, GR, IE, PL, PT)	(CAS No) 56-81-5 (EC no) 200-289-5	1-5	Not classified
Name	Product Identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Zinc oxide	(CAS No) 1314-13-2 (EC no) 215-222-5 (EC index no) 030-013-00-7	70 - 90	Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Castor oil	(CAS No) 8001-79-4 (EC no) 232-293-8	10 - 20	Eye Irrit. 2, H319
Glycerin substance with national workplace exposure limit(s) (BE, CZ, ES, ET, FI, FR, GB, GR, IE, PL, PT)	(CAS No) 56-81-5 (EC no) 200-289-5	1-5	Not classified

Full text of R- and H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of First Aid Measures

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

seek medical advice (show the label where possible).

First-aid measures after inhalation : Not expected to present a significant inhalation hazard under anticipated

conditions of normal use.

First-aid measures after skin contact : Remove contaminated clothing. Drench affected area with water for at least

15 minutes. Wash contaminated clothing before reuse. Seek medical

attention if ill effect or irritation develops.

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

present and easy to do. Continue rinsing. Immediately call a POISON CENTER

or doctor/physician.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or

doctor/physician.

4.2. Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms/injuries : Causes eye irritation.

Symptoms/injuries after inhalation : None expected under normal conditions of use. Symptoms/injuries after skin contact : None expected under normal conditions of use.

Symptoms/injuries after eye contact : Causes eye irritation.

09/07/2014 EN (English) 2/8

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Symptoms/injuries after ingestion : May be harmful if swallowed.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention.

SECTION 5: Firefighting measures

5.1. Extinguishing Media

Suitable extinguishing media : Dry chemical powder, alcohol foam, carbon dioxide, water spray, fog.

Unsuitable extinguishing media : Do not use a heavy water stream. Use of heavy stream of water may spread

fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire hazard : Not considered flammable but may burn at high temperatures.

Explosion hazard : Heat may build pressure, rupturing closed containers, spreading fire and

increasing risk of burns and injuries.

Reactivity : No reactivity hazard.

5.3. Advice for firefighters

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

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

respiratory protection.

Other information : Refer to Section 9 for flammability properties.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid all contact with skin, eyes, or clothing.

6.1.1. For non-emergency personnel

Protective equipment : Use appropriate personal protection equipment (PPE).

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Absorb and contain spill with inert material, then place in suitable container.

Methods for cleaning up : Clear up spills immediately and dispose of waste safely.

6.4. Reference to other sections

See heading 8, Exposure Controls and Personal Protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures.

Wash hands and other exposed areas with mild soap and water before

eating, drinking, or smoking and again when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a dry, cool and well-ventilated place. Keep container closed when

not in use.

Incompatible products : Strong acids. Strong bases. Strong oxidizers.

7.3. Specific end use(s)

For temporary restorative treatment. For professional dental use only.

09/07/2014 EN (English) 3/8

Safety Data Sheet according to Regulation (EC) No. 453/2010

SECTION 8: Exposure controls/personal protection

Control parameters 8.1.

Zinc oxide (1314-13-2)		
Austria	MAK (mg/m³)	5 mg/m³
Belgium	Limit value (mg/m³)	5 mg/m³
Belgium	Short time value (mg/m³)	10 mg/m³
Bulgaria	OEL TWA (mg/m³)	5.0 mg/m³
Bulgaria	OEL STEL (mg/m³)	10.0 mg/m³
France	VME (mg/m³)	10 mg/m³
Italy - Portugal - USA ACGIH	ACGIH TWA (mg/m³)	2 mg/m³
Italy - Portugal - USA ACGIH	ACGIH STEL (mg/m³)	10 mg/m³
Latvia	OEL TWA (mg/m³)	0.5 mg/m³
Spain	VLA-ED (mg/m³)	2 mg/m³
Spain	VLA-EC (mg/m³)	10 mg/m³
Czech Republic	Expoziční limity (PEL) (mg/m³)	2 mg/m³
Denmark	Grænseværdie (langvarig) (mg/m³)	4 mg/m³
Finland	HTP-arvo (8h) (mg/m³)	2 mg/m³
Finland	HTP-arvo (15 min)	10 mg/m ³
Hungary	AK-érték	5 mg/m³
Hungary	CK-érték	20 mg/m ³
Ireland	OEL (8 hours ref) (mg/m³)	2 mg/m³
Ireland	OEL (15 min ref) (mg/m3)	10 mg/m ³
Lithuania	IPRV (mg/m³)	5 mg/m³
Poland	NDS (mg/m³)	5 mg/m³
Poland	NDSCh (mg/m³)	10 mg/m ³
Romania	OEL TWA (mg/m³)	5 mg/m³
Romania	OEL STEL (mg/m³)	10 mg/m ³
Slovakia	NPHV (priemerná) (mg/m³)	1 mg/m³
Slovakia	NPHV (Hraničná) (mg/m³)	1 mg/m³
Sweden	nivågränsvärde (NVG) (mg/m³)	5 mg/m³
Portugal	OEL TWA (mg/m³)	2 mg/m³
Portugal	OEL STEL (mg/m³)	10 mg/m ³
Glycerin (56-81-5)		
Belgium	Limit value (mg/m³)	10 mg/m ³
France	VME (mg/m³)	10 mg/m ³
Spain	VLA-ED (mg/m³)	10 mg/m ³
United Kingdom	WEL TWA (mg/m³)	10 mg/m³
United Kingdom	WEL STEL (mg/m³)	30 mg/m³ (calculated)
Czech Republic	Expoziční limity (PEL) (mg/m³)	10 mg/m³
Finland	HTP-arvo (8h) (mg/m³)	20 mg/m³
Ireland	OEL (8 hours ref) (mg/m³)	10 mg/m³
Poland	NDS (mg/m³)	10 mg/m³
Portugal	OEL TWA (mg/m³)	10 mg/m³

09/07/2014 EN (English) 4/8

Safety Data Sheet

according to Regulation (EC) No. 453/2010

8.2. Exposure controls

Appropriate engineering controls : Emergency eye wash fountains and safety showers should be available in the

immediate vicinity of any potential exposure.

Personal protective equipment : Safety glasses. Gloves. Protective clothing.







Hand protection : Wear chemically resistant protective gloves.

Eye protection : Chemical goggles or safety glasses. Skin and body protection : Wear suitable protective clothing.

Respiratory protection : Use a NIOSH-approved respirator or self-contained breathing apparatus

whenever exposure may exceed established Occupational Exposure Limits.

Other information : When using, do not eat, drink or smoke.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid (paste) Colour : No data available Odour No data available Odour threshold : No data available рН : No data available Relative evaporation rate (butylacetate=1) : No data available Melting point : No data available Freezing point : No data available : No data available **Boiling point** Flash point : No data available : No data available Auto-ignition temperature Decomposition temperature : No data available Flammability (solid, gas) : No data available : No data available Vapour pressure Relative vapour density at 20 °C : No data available : No data available **Relative Density** : No data available Solubility Partition coefficient: n-octanol/water : No data available Viscosity, kinematic : No data available

9.2. Other information

VOC content : < 1 %

SECTION 10: Stability and reactivity

10.1. Reactivity

Viscosity, dynamic

Explosive properties

Oxidising properties

Explosive limits

No reactivity hazard.

10.2. Chemical stability

Product is stable.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

09/07/2014 EN (English) 5/8

: No data available

: No data available

: No data available

: Not applicable

Safety Data Sheet

according to Regulation (EC) No. 453/2010

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizers.

10.6. Hazardous decomposition products

Hydrocarbons. Carbon oxides (CO, CO₂). Oxides of zinc.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Zinc oxide (1314-13-2)		
LD50 oral rat	> 5000 mg/kg	
ATE (dust,mist) 5.800 mg/l/4h		
Glycerin (56-81-5)		
LD50 dermal rabbit	> 10 g/kg	
LC50 inhalation rat (mg/l)	> 570 mg/m³ (Exposure time: 1 h)	

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Causes serious eye irritation.

Respiratory or skin sensitisation : Not classified Germ cell mutagenicity : Not classified Carcinogenicity : Not classified Reproductive toxicity : Not classified

Specific target organ toxicity (single exposure) : Not classified Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Zinc oxide (1314-13-2)	
LC50 fishes 1	780 μg/l Pimephales promelas
NOEC chronic fish	0.026 mg/l Jordanella floridae
Glycerin (56-81-5)	
LC50 fishes 1	51 (51 - 57) ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Glycerin (56-81-5)		
BCF fish 1	(no bioaccumulation)	
Log Pow	-1.76	

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of waste material in accordance with all local, regional, national,

provincial, territorial and international regulations.

09/07/2014 EN (English) 6/8

Safety Data Sheet

according to Regulation (EC) No. 453/2010

SECTION 14: Transport information

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

14.1. UN number

UN-No (ADR) : 3082

14.2. UN proper shipping name

Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

Transport document description : UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

(Contains Zinc Oxide), 9, III, (E)

14.3. Transport hazard class(es)

Class (UN) : 9 Hazard labels (UN) : 9



14.4. Packing group

Packing group (UN) : III

14.5. Environmental hazards

Dangerous for the environment



14.6. Special precautions for user

14.6.1. Overland transport

Hazard identification number (Kemler: 90

No.)

Classification code (UN) : M6

Orange plates :

90 3082

Special provision (ADR) 274, 335, 601

Transport category (ADR) 3
Tunnel restriction code : E
Limited quantities (ADR) 5L
Excepted quantities (ADR) : E1
EAC code : •3Z

14.6.2. Transport by sea

MFAG-No : 171

14.6.3. Air transport

No additional information available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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

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

3. Liquid substances or mixtures which are regarded as dangerous in accordance with
Directive 1999/45/EC or are fulfilling the criteria for any of the following hazard classes
or categories set out in Annex I to Regulation (EC) No 1272/2008

Contains no REACH candidate substance

VOC content : < 1 %

09/07/2014 EN (English) 7/8

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Other information, restriction and prohibition regulations

: This substance is for use in medicinal products, and as such, is exempt from REACH registration requirements.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Revision date : 09/07/2014

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

 $\label{ling} \mbox{ December 2008 on classification, labelling and packaging of substances and mixtures, amending and labelling and packaging of substances and mixtures. \\$

repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Full text of R-, H- and EUH-phrases:

Aquatic Acute 1	Hazardous to the aquatic environment — AcuteHazard, Category 1	
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
H319	Causes serious eye irritation	
H400	Very toxic to aquatic life	
H410	Very toxic to aquatic life with long lasting effects	
R36	Irritating to eyes	
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment	
N	Dangerous for the environment	
Xi	Irritant	

SDS EU (REACH Annex II)

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

09/07/2014 EN (English) 8/8

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Revision date: 09/07/2014 Date of issue: 09/07/2014

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

1.1. Product Identifier

Product form : Mixture

Product Name : DE Healthcare Temporary Cement Zincoxide Eugenol catalyst, 20g, REF 9796643

Synonyms : ZOE Eugenol Temporary Cement A

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional dental use only.

Use of the substance/mixture : For temporary restorative treatment.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

DE Healthcare Ltd., Unit 9, Kingsthorpe Business Centre, Studland Road, Kingsthorpe, Northampton NN2 6NE U.K. **Tel.:** +44 1634 266 056 **E-Mail:** info@dehpbrand.com

1.4. Emergency Telephone Number

Emergency #: Chemtrec US (800) 424-9300 EU Tel.: 112 International: 001 703-527-3887 Suisse: 145

SECTION 2: Hazards identification

2.1. Classification of the Substance or Mixture

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

Eye Irrit. 2 H319 Skin Sens. 1 H317

Full text of H-phrases: see section 16

Classification according to Directive 67/548/EEC or 1999/45/EC

Xi; R36 R43

Full text of R-phrases: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label Elements

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

Hazard pictograms (CLP)

GHS07

Signal word (CLP) : Warning Hazardous ingredients : Eugenol

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

H319 - Causes serious eye irritation

Precautionary statements (CLP) P261 - Avoid breathing dust, mist, spray, vapours.

P264 - Wash hands, forearms, and exposed areas thoroughly after handling.

P272 - Contaminated work clothing should not be allowed out of the

workplace.

P280 - Wear eye protection, protective clothing, protective gloves.

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

09/07/2014 EN (English) 1/6

Version: 1.0

Safety Data Sheet

according to Regulation (EC) No. 453/2010

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several

minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P321 - Specific treatment (see Section 4 on this label).

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 according to local, regional, national,

and international regulations.

2.3. Other Hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	Classification according to Directive 67/548/EEC
Eugenol	(CAS No) 97-53-0	20 - 30	Xn; R22
	(EC no) 202-589-1		Xi; R36
			R43
Name	Product Identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Eugenol	(CAS No) 97-53-0	20 - 30	Acute Tox. 4 (Oral), H302
	(EC no) 202-589-1		Eye Irrit. 2, H319
1			Skin Sens. 1, H317

Full text of R- and H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of First Aid Measures

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

seek medical advice (show the label where possible).

First-aid measures after inhalation : Not expected to present a significant inhalation hazard under anticipated

conditions of normal use.

First-aid measures after skin contact : Remove contaminated clothing. Drench affected area with water for at least

15 minutes. Wash contaminated clothing before reuse. Seek medical

attention if ill effect or irritation develops.

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

present and easy to do. Continue rinsing. Immediately call a POISON CENTER

or doctor/physician.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or

doctor/physician.

4.2. Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms/injuries : Exposure may produce an allergic reaction. Causes severe irritation to eyes

and skin

Symptoms/injuries after inhalation : None expected under normal conditions of use.

Symptoms/injuries after skin contact : May cause an allergic skin reaction.

Symptoms/injuries after eye contact : Causes eye irritation.

Symptoms/injuries after ingestion : May be harmful if swallowed.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention.

SECTION 5: Firefighting measures

5.1. Extinguishing Media

Suitable extinguishing media : Dry chemical powder, alcohol foam, carbon dioxide, water spray, fog.

09/07/2014 EN (English) 2/6

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Unsuitable extinguishing media : Do not use a heavy water stream. Use of heavy stream of water may spread

fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire hazard : Not considered flammable but may burn at high temperatures.

Explosion hazard : Product is not explosive. Reactivity : No reactivity hazard.

5.3. Advice for firefighters

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

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

respiratory protection.

Other information : Refer to Section 9 for flammability properties.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid all contact with skin, eyes, or clothing.

6.1.1. For non-emergency personnel

Protective equipment : Use appropriate personal protection equipment (PPE).

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Absorb and/or contain spill with inert material, then place in suitable

container.

Methods for cleaning up : Clear up spills immediately and dispose of waste safely.

6.4. Reference to other sections

See heading 8, Exposure Controls and Personal Protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures.

Wash hands and other exposed areas with mild soap and water before

eating, drinking, or smoking and again when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a dry, cool and well-ventilated place. Keep container closed when

not in use.

Incompatible products : Strong acids. Strong bases. Strong oxidizers.

7.3. Specific end use(s)

For temporary restorative treatment. For professional dental use only.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls : Emergency eye wash fountains and safety showers should be available in the

immediate vicinity of any potential exposure.

Personal protective equipment : Safety glasses. Gloves. Protective clothing.







09/07/2014 EN (English) 3/6

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Hand protection : Wear chemically resistant protective gloves.

Eye protection : Chemical goggles or safety glasses.
Skin and body protection : Wear suitable protective clothing.

Respiratory protection : Use a NIOSH-approved respirator or self-contained breathing apparatus

whenever exposure may exceed established Occupational Exposure Limits.

Other information : When using, do not eat, drink or smoke.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid (paste) Colour : No data available Odour : No data available Odour threshold : No data available : No data available На Relative evaporation rate (butylacetate=1) : No data available : No data available Melting point Freezing point : No data available **Boiling point** : No data available Flash point : No data available : No data available Auto-ignition temperature : No data available Decomposition temperature Flammability (solid, gas) : No data available Vapour pressure : No data available Relative vapour density at 20 °C : No data available **Relative Density** : No data available : No data available Solubility Partition coefficient: n-octanol/water : No data available

Viscosity, kinematic : No data available
Viscosity, dynamic : No data available
Explosive properties : No data available
Oxidising properties : No data available
Explosive limits : No data available
: No data available

9.2. Other information

VOC content : < 1 %

SECTION 10: Stability and reactivity

10.1. Reactivity

No reactivity hazard.

10.2. Chemical stability

Product is stable.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizers.

10.6. Hazardous decomposition products

Hydrocarbons. Carbon oxides (CO, CO₂).

09/07/2014 EN (English) 4/6

Safety Data Sheet

according to Regulation (EC) No. 453/2010

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

 Eugenol (97-53-0)

 LD50 oral rat
 1930 mg/kg

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Causes serious eye irritation.

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

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

Specific target organ toxicity (single exposure) : Not classified Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of waste material in accordance with all local, regional, national,

provincial, territorial and international regulations.

SECTION 14: Transport information

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

14.1. UN number

No dangerous good in sense of transport regulations

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Other information : No supplementary information available.

14.6. Special precautions for user

Not applicable

14.6.1. Overland transport

14.6.2. Transport by sea

Not applicable

09/07/2014 EN (English) 5/6

Safety Data Sheet

according to Regulation (EC) No. 453/2010

14.6.3. Air transport

No additional information available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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

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

	• •
3. Liquid substances or mixtures which are regarded as dangerous in accordance with	ZOE Temporary
Directive 1999/45/EC or are fulfilling the criteria for any of the following hazard class-	es or Cement Catalyst -
categories set out in Annex I to Regulation (EC) No 1272/2008	Eugenol
40. Substances classified as flammable gases category 1 or 2, flammable liquids categ	ories ZOE Temporary
1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact	t with Cement Catalyst
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 REACH candidate substance

VOC content : < 1 %

Other information, restriction and : This substance is for use in medicinal products, and as such, is exempt from

prohibition regulations REACH registration requirements.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Revision date: 09/07/2014

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 R-, H- and EUH-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Sens. 1	Sensitisation — Skin, category 1
H302	Harmful if swallowed
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
R10	Flammable
R22	Harmful if swallowed
R36	Irritating to eyes
R43	May cause sensitisation by skin contact
Xi	Irritant
Xn	Harmful

SDS EU (REACH Annex II)

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

09/07/2014 EN (English) 6/6