Printing date 18.04.2013 Version number 2 Revision: 18.04.2013

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

- · 1.1 Product identifier
- · Trade name: Kalsogen Plus Liquid
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

- · Application of the substance / the preparation Zinc eugenol cement
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

DENTSPLY DeTrey GmbH

De-Trey-Str. 1

D-78467 Konstanz

**GERMANY** 

*Tel.*: +49-(0)7531-583-0 *Fax*: +49-(0)7531-583-104

email: KonstanzDEU.info-sdb@dentsply.com

- · Further information obtainable from:
- Departement Analytical Research / Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets
- 1.4 Emergency telephone number: +49-(0)7531-583-0 8:00 17:00 (GMT + 1:00)

#### 2 Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC

Xi; Irritant

R36: Irritating to eyes.

Xi; Sensitising

R43: May cause sensitisation by skin contact.

· Information concerning particular hazards for human and environment:

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

· Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- · 2.2 Label elements
- · Labelling according to EU guidelines:

The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials

· Code letter and hazard designation of product:



Xi Irritant

· Hazard-determining components of labelling:

Eugenol

- · Risk phrases:
- 36 Irritating to eyes.
- 43 May cause sensitisation by skin contact.
- · Safety phrases:
- 23 Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer).

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Printing date 18.04.2013 Version number 2 Revision: 18.04.2013

Trade name: Kalsogen Plus Liquid

(Contd. of page 1)

- 24 Avoid contact with skin.
- 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- 37 Wear suitable gloves.
- 60 This material and its container must be disposed of as hazardous waste.
- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

#### 3 Composition/information on ingredients

- · 3.2 Chemical characterization: Mixtures
- · **Description:** Mixture of substances listed below with nonhazardous additions.
- · Dangerous components:

· Additional information For the wording of the listed risk phrases refer to section 16.

### 4 First aid measures

- · 4.1 Description of first aid measures
- · After inhalation Supply fresh air; consult doctor in case of complaints.
- · After skin contact Immediately wash with water and soap and rinse thoroughly.
- · After eye contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· After swallowing

Rinse out mouth and then drink plenty of water.

Induce vomiting and call for medical help.

- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

#### 5 Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents

CO2, powder or water spray. Fight larger fire with alcohol resistant foam.

*Use fire extinguishing methods suitable to surrounding conditions.* 

· 5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

- · 5.3 Advice for firefighters
- · Protective equipment: Self-contained respiratory protective device.

#### 6 Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation

Wear protective clothing.

• 6.2 Environmental precautions: Do not allow to enter sewers/surface or ground water.

(Contd. on page 3)

Printing date 18.04.2013 Version number 2 Revision: 18.04.2013

Trade name: Kalsogen Plus Liquid

(Contd. of page 2)

· 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Ensure adequate ventilation.

· 6.4 Reference to other sections

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

#### 7 Handling and storage

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Observe normal care for working with chemicals.

- · Handling Product is intended for dental use only.
- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage
- Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Keep receptacle tightly sealed.

Protect from heat and direct sunlight.

· 7.3 Specific end use(s) No further relevant information available.

### 8 Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment
- · General protective and hygienic measures

The usual precautionary measures are to be adhered to when handling chemicals.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

- Respiratory protection: Not necessary if room is well-ventilated.
- · Protection of hands:



Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

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Trade name: Kalsogen Plus Liquid

(Contd. of page 3)

#### · Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. Butyl rubber, BR

Recommended thickness of the material:  $\geq 0.5$  mm

*Permeation: Level ≥6* 

#### · Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Not suitable are gloves made of the following materials:

Natural rubber, NR Nitrile rubber, NBR PVC gloves

· Eye protection: Safety glasses



· Density at 20 °C:

Tightly sealed goggles.

· Body protection: Protective work clothing.

9 Physical and chemical properties

9.1 Information on basic physical a	and chamical proporties	
General Information	una cnemicai properties	
Appearance:		
Form:	Liquid	
Colour:	Yellowish	
Odour:	Characteristic	
Odour threshold:	Not determined.	
pH-value:	Not determined.	
Change in condition		
Melting point/Melting range:	undetermined	
Boiling point/Boiling range:	253 °C	
Flash point:	116 °C	
Flammability (solid, gaseous)	Not applicable.	
Ignition temperature:		
Decomposition temperature:	Not determined.	
Self-igniting:	Product is not selfigniting.	
Danger of explosion:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
Vapour pressure:	Not determined.	

 $1.02 \ g/cm^3$ 

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Trade name: Kalsogen Plus Liquid

(Contd. of page 4)

Relative density
Vapour density
Evaporation rate
Not determined.
Not determined.
Not determined.

· Solubility in / Miscibility with

Water: Not miscible or difficult to mix

· Partition coefficient (n-octanol/water): Not determined.

· Viscosity:

dynamic: Not determined. kinematic: Not determined.

· Solvent content:

Organic solvents: 0.0 %

• 9.2 Other information No further relevant information available.

### 10 Stability and reactivity

- · 10.1 Reactivity
- · 10.2 Chemical stability
- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known
- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known

#### 11 Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity:
- · LD/LC50 values relevant for classification:

97-53-0 Eugenol

Oral LD50 2680 mg/kg (rat)

- · Primary irritant effect:
- · on the skin: may cause skin irritation
- · on the eye: Irritating effect.
- · Sensitization: Sensitization possible through skin contact.
- · Additional toxicological information:

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

Irritant

### 12 Ecological information

· 12.1 Toxicity

· Aquatic toxicity:
97-53-0 Eugenol

EC50/48h 1.05 mg/L (daphnia)

LC50/96h | 66.1 mg/l (fish)

(Contd. on page 6)

Printing date 18.04.2013 Version number 2 Revision: 18.04.2013

Trade name: Kalsogen Plus Liquid

(Contd. of page 5)

- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · 12.5 Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

### 13 Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation



Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

18 01 06\* chemicals consisting of or containing dangerous substances

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

· 14.1 UN-Number · ADR, ADN, IMDG, IATA	Void
· · · · · · · · · · · · · · · · · · ·	1014
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	Void
· 14.4 Packing group	
· ADR, IMDG, IATA	Void
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of	r
MARPOL73/78 and the IBC Code	Not applicable.

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(Contd. on page 7)

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Trade name: Kalsogen Plus Liquid

(Contd. of page 6)

#### 15 Regulatory information

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

### 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

· Relevant phrases

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

R36 Irritating to eyes.

R43 May cause sensitisation by skin contact.

- · Department issuing MSDS: Analytical Research
- · Contact: HotLine for urgent technical support: +49-7531-583-333
- \* Data compared to the previous version altered.

GB

Printing date 18.04.2013 Version number 2 Revision: 18.04.2013

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

- · 1.1 Product identifier
- · Trade name: Kalsogen Plus Powder
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

- · Application of the substance / the preparation Zinc eugenol cement
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

DENTSPLY DeTrey GmbH

De-Trey-Str. 1

D-78467 Konstanz

**GERMANY** 

*Tel.*: +49-(0)7531-583-0 *Fax*: +49-(0)7531-583-104

email: KonstanzDEU.info-sdb@dentsply.com

- · Further information obtainable from:
- Departement Analytical Research / Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets
- 1.4 Emergency telephone number: +49-(0)7531-583-0 8:00 17:00 (GMT + 1:00)

#### 2 Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC

N; Dangerous for the environment

R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

· Information concerning particular hazards for human and environment:

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

· Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- · 2.2 Label elements
- · Labelling according to EU guidelines:

The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials

· Code letter and hazard designation of product:



 $N\,Dangerous\,for\,the\,environment$ 

· Risk phrases:

50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

- · Safety phrases:
- 57 Use appropriate container to avoid environmental contamination.
- 60 This material and its container must be disposed of as hazardous waste.
- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.

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Printing date 18.04.2013 Version number 2 Revision: 18.04.2013

Trade name: Kalsogen Plus Powder

· vPvB: Not applicable.

(Contd. of page 1)

#### 3 Composition/information on ingredients

- · 3.2 Chemical characterization: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:

CAS: 1314-13-2 zinc oxide EINECS: 215-222-5 N R50/53

Aquatic Acute 1, H400; Aquatic Chronic 1, H410

50-100%

· Additional information For the wording of the listed risk phrases refer to section 16.

#### 4 First aid measures

- · 4.1 Description of first aid measures
- · After inhalation Supply fresh air; consult doctor in case of complaints.
- · After skin contact Generally the product does not irritate the skin.
- · After eye contact Rinse opened eye for several minutes under running water.
- · After swallowing Void
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

### 5 Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

#### 6 Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

Wear protective clothing.

· 6.2 Environmental precautions:

Inform respective authorities in case of seepage into water course or sewage system.

Do not allow to enter sewers/ surface or ground water.

· 6.3 Methods and material for containment and cleaning up:

Pick up mechanically.

Dispose of the material collected according to regulations.

· 6.4 Reference to other sections

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

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Printing date 18.04.2013 Version number 2 Revision: 18.04.2013

Trade name: Kalsogen Plus Powder

(Contd. of page 2)

#### 7 Handling and storage

- · 7.1 Precautions for safe handling Observe normal care for working with chemicals.
- · Handling Product is intended for dental use only.
- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage
- Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: None.
- · 7.3 Specific end use(s) No further relevant information available.

### 8 Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment
- · General protective and hygienic measures

The usual precautionary measures are to be adhered to when handling chemicals.

- **Respiratory protection:** Not necessary if room is well-ventilated.
- · Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection: Safety glasses

· Body protection: Protective work clothing.

#### 9 Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Powder Colour: White

· Odour: Product specific

(Contd. on page 4)

Printing date 18.04.2013 Version number 2 Revision: 18.04.2013

Trade name: Kalsogen Plus Powder

		(Contd. of page
· Odour threshold:	Not determined.	
· pH-value:	Not applicable.	
· Change in condition		
Melting point/Melting range:	undetermined	
Boiling point/Boiling range:	undetermined	
· Flash point:	Not applicable	
· Flammability (solid, gaseous)	Not determined.	
· Ignition temperature:		
Decomposition temperature:	Not determined.	
· Self-igniting:	Product is not selfigniting.	
Danger of explosion:	Product does not present an explosion hazard.	
· Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
Vapour pressure:	Not applicable.	
· Density:	Not determined	
Relative density	Not determined.	
· Vapour density	Not applicable.	
Evaporation rate	Not applicable.	
· Solubility in / Miscibility with		
Water:	Insoluble	
Partition coefficient (n-octanol/wa	ter): Not determined.	
· Viscosity:		
dynamic:	Not applicable.	
kinematic:	Not applicable.	
· Solvent content:		
Organic solvents:	0.0 %	
Solids content:	100.0 %	
· 9.2 Other information	No further relevant information available.	

### 10 Stability and reactivity

- · 10.1 Reactivity
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known
- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known

Printing date 18.04.2013 Version number 2 Revision: 18.04.2013

Trade name: Kalsogen Plus Powder

(Contd. of page 4)

#### 11 Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity:
- · LD/LC50 values relevant for classification:

1314-13-2 zinc oxide

Oral LD50 >5000 mg/kg (rat)

- · Primary irritant effect:
- · on the skin: No irritant effect.
- · on the eye: No irritating effect.
- · Sensitization: No sensitizing effects known.

### 12 Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity:

1314-13-2 zinc oxide

EC50/48h 0.098 mg/L (daphnia)

LC50/96h 1.1 mg/l (fish)

- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Ecotoxical effects:
- · Remark: Very toxic for fish
- · Additional ecological information:
- · General notes:

Also poisonous for fish and plankton in water bodies.

Very toxic for aquatic organisms

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

- · 12.5 Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

#### 13 Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation



Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

18 01 06\* chemicals consisting of or containing dangerous substances

(Contd. on page 6)

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Trade name: Kalsogen Plus Powder

(Contd. of page 5)

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

14.1 UN-Number	
ADR, IMDG, IATA	UN3077
14.2 UN proper shipping name	
ADR	3077 ENVIRONMENTALLY HAZARDOUS SUBSTANC
ADK	SOLID, N.O.S. (zinc oxide)
· IMDG · IATA	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLI
	N.O.S. (zinc oxide), MARINE POLLUTANT
	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLI
	N.O.S. (zinc oxide)
14.3 Transport hazard class(es)	
ADR	
Class	9 (M7) Miscellaneous dangerous substances and articles.
Label	9
IMDG, IATA	
Class Label	9 Miscellaneous dangerous substances and articles.
	,
14.4 Packing group ADR, IMDG, IATA	III
* * *	111
14.5 Environmental hazards:	TV.
Marine pollutant:	Yes
Special marking (ADR):	Symbol (fish and tree) Symbol (fish and tree)
Special marking (ADA): Special marking (IATA):	Symbol (fish and tree)
<u> </u>	Warning: Miscellaneous dangerous substances and articles.
14.6 Special precautions for user Danger code (Kemler):	90
EMS Number:	F-A,S-F
14.7 Transport in bulk according to Anne MARPOL73/78 and the IBC Code	
Transport/Additional information:	
444-44	
Limited quantities (LQ)	5 kg

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Printing date 18.04.2013 Version number 2 Revision: 18.04.2013

Trade name: Kalsogen Plus Powder

(Contd. of page 6)

· Tunnel restriction code

Е

### 15 Regulatory information

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

#### 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

· Relevant phrases

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

- · Department issuing MSDS: Analytical Research
- · Contact: HotLine for urgent technical support: +49-7531-583-333
- \* \* Data compared to the previous version altered.

GB ·