

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 26.03.2015

Version number 4

Revision: 26.03.2015

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

#### 1.1 Product identifier

· Trade name: **ViscoGel Liquid**

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

· Application of the substance / the mixture *Impression material*

· Uses advised against *No further relevant information available.*

#### 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

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##### 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)

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

· Classification according to Regulation (EC) No 1272/2008

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Acute Tox. 4 H332 Harmful if inhaled.

#### 2.2 Label elements

· Labelling according to Regulation (EC) No 1272/2008

As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation 1272/2008.

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms



GHS02 GHS07

· Signal word *Danger*

· Hazard-determining components of labelling:

triethyl citrate

· Hazard statements

H225 Highly flammable liquid and vapour.

H332 Harmful if inhaled.

· Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P241 Use explosion-proof electrical/ventilating/lighting/equipment.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

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P403+P235 Store in a well-ventilated place. Keep cool.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

|                                   |                  |                      |         |
|-----------------------------------|------------------|----------------------|---------|
| CAS: 77-93-0<br>EINECS: 201-070-7 | triethyl citrate | ⚠ Acute Tox. 4, H332 | 50-100% |
| CAS: 64-17-5<br>EINECS: 200-578-6 | ethanol          | ⚠ Flam. Liq. 2, H225 | 3-<10%  |

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

**SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
- **General information**  
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **After inhalation**  
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
- **After skin contact** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact** Rinse opened eye for several minutes under running water.
- **After swallowing** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Information for doctor** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

**SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
- **Suitable extinguishing agents** CO<sub>2</sub>, sand, extinguishing powder. Do not use water.
- **For safety reasons unsuitable extinguishing agents** Water.
- **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:** Mount respiratory protective device.

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### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Dispose contaminated material as waste according to item 13.  
Ensure adequate ventilation.  
Do not flush with water or aqueous cleansing agents
- **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.

### SECTION 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:**



Keep ignition sources away - Do not smoke.

- Protect against electrostatic charges.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Store away from oxidising agents.
- **Further information about storage conditions:** Store in cool, dry conditions in well sealed receptacles.
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 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:**

**64-17-5 ethanol**

WEL Long-term value: 1920 mg/m<sup>3</sup>, 1000 ppm

· **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.

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- **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 through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:**



Tightly sealed goggles.

- **Body protection:** Protective work clothing.

### SECTION 9: Physical and chemical properties

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

##### · General Information

##### · Appearance:

|                           |                 |
|---------------------------|-----------------|
| · <b>Form:</b>            | Fluid           |
| · <b>Colour:</b>          | Colourless      |
| · <b>Odour:</b>           | Like alcohol    |
| · <b>Odour threshold:</b> | Not determined. |

· **pH-value:** Not determined.

##### · Change in condition

|                                       |              |
|---------------------------------------|--------------|
| · <b>Melting point/Melting range:</b> | undetermined |
| · <b>Boiling point/Boiling range:</b> | 109 °C       |

· **Flash point:** 18 °C (c.c)

· **Flammability (solid, gaseous)** Not applicable.

· **Ignition temperature:** 425 °C

· **Decomposition temperature:** Not determined.

· **Self-igniting:** Product is not selfigniting.

· **Danger of explosion:** Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

##### · Explosion limits:

|                 |                 |
|-----------------|-----------------|
| · <b>Lower:</b> | Not determined. |
| · <b>Upper:</b> | Not determined. |

· **Vapour pressure:** Not determined.

· **Density at 20 °C:** 1.11 g/cm<sup>3</sup>

· **Relative density** Not determined.

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- |   |  |
|---|--|
| · <b>Vapour density</b>                           | Not determined.                            |
| · <b>Evaporation rate</b>                         | Not determined.                            |
| · <b>Solubility in / Miscibility with Water:</b>  | Partly miscible                            |
| · <b>Partition coefficient (n-octanol/water):</b> | Not determined.                            |
| · <b>Viscosity:</b>                               |  |
| <b>dynamic:</b>                                   | Not determined.                            |
| <b>kinematic:</b>                                 | Not determined.                            |
| · <b>Solvent content:</b>                         |  |
| <b>Organic solvents:</b>                          | 7.0 %                                      |
| · <b>9.2 Other information</b>                    | No further relevant information available. |

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **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:** strong oxidants
- **10.6 Hazardous decomposition products:** Carbon monoxide and carbon dioxide

**SECTION 11: Toxicological information**

- **11.1 Information on toxicological effects**
- **Acute toxicity:**

· **LD/LC50 values relevant for classification:**

**ATE (Acute Toxicity Estimates)**

|            |          |           |
|------------|----------|-----------|
| Inhalative | LC50/4 h | 11.7 mg/l |
|------------|----------|-----------|

**77-93-0 triethyl citrate**

|            |          |                      |
|------------|----------|----------------------|
| Oral       | LD50     | 5900 mg/kg (rat)     |
| Dermal     | LD50     | >5000 mg/kg (rabbit) |
| Inhalative | LC50/4 h | 11 mg/l (ATE)        |

**64-17-5 ethanol**

|            |          |                  |
|------------|----------|------------------|
| Oral       | LD50     | 6200 mg/kg (rat) |
| Inhalative | LC50/4 h | 95.6 mg/l (rat)  |

- **Primary irritant effect:**
- **on the skin:** may cause skin irritation
- **on the eye:** Irritating effect.
- **Sensitisation:** No sensitising effects known.
- **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.

Harmful

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### SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

**64-17-5 ethanol**

EC50/48h 9268 mg/L (*daphnia magna*)

LC50/48h 8140 mg/l (*Fish acute toxicity study*)

· **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.

### SECTION 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.

### SECTION 14: Transport information

· **14.1 UN-Number**

· **ADR, IMDG, IATA**

UN1170

· **14.2 UN proper shipping name**

· **ADR**

1170 ETHANOL (ETHYL ALCOHOL), mixture

· **IMDG**

ETHANOL (ETHYL ALCOHOL) mixture

· **IATA**

ETHANOL mixture

· **14.3 Transport hazard class(es)**

· **ADR**



· **Class**

3 (F1) Flammable liquids.

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|  |   |
|--|---|
| · <b>Label</b>   | 3   |
| · <b>IMDG, IATA</b>  |   |
|                     |   |
| · <b>Class</b>   | 3 Flammable liquids.  |
| · <b>Label</b>   | 3   |
| · <b>14.4 Packing group</b><br>· <b>ADR, IMDG, IATA</b>  | II  |
| · <b>14.5 Environmental hazards:</b><br>· <b>Marine pollutant:</b>                                   | No  |
| · <b>14.6 Special precautions for user</b><br>· <b>Danger code (Kemler):</b><br>· <b>EMS Number:</b> | Warning: Flammable liquids.<br>33<br>F-E,S-D  |
| · <b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>                | Not applicable.   |
| · <b>Transport/Additional information:</b>   |   |
| · <b>ADR</b><br>· <b>Limited quantities (LQ)</b><br>· <b>Excepted quantities (EQ)</b>                | 1L<br>Code: E2<br>Maximum net quantity per inner packaging: 30 ml<br>Maximum net quantity per outer packaging: 500 ml |
| · <b>Transport category</b><br>· <b>Tunnel restriction code</b>                                      | 2<br>D/E  |
| · <b>IMDG</b><br>· <b>Limited quantities (LQ)</b><br>· <b>Excepted quantities (EQ)</b>               | 1L<br>Code: E2<br>Maximum net quantity per inner packaging: 30 ml<br>Maximum net quantity per outer packaging: 500 ml |
| · <b>UN "Model Regulation":</b>  | UN1170, ETHANOL (ETHYL ALCOHOL) mixture, 3, II  |

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 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.

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*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***H225 Highly flammable liquid and vapour.**H332 Harmful if inhaled.***· Department issuing MSDS: Analytical Research****· Contact: HotLine for urgent technical support: +49-7531-583-350****· Abbreviations and acronyms:***ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)**IMDG: International Maritime Code for Dangerous Goods**IATA: International Air Transport Association**GHS: Globally Harmonised System of Classification and Labelling of Chemicals**EINECS: European Inventory of Existing Commercial Chemical Substances**ELINCS: European List of Notified Chemical Substances**CAS: Chemical Abstracts Service (division of the American Chemical Society)**LC50: Lethal concentration, 50 percent**LD50: Lethal dose, 50 percent**Flam. Liq. 2: Flammable liquids, Hazard Category 2**Acute Tox. 4: Acute toxicity, Hazard Category 4***· \* Data compared to the previous version altered.**

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

- **1.1 Product identifier**
- **Trade name:** *Visco-Gel Powder*
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** *Impression material*
- **Uses advised against** *No further relevant information available.*
- **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)*

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
  - **Classification according to Regulation (EC) No 1272/2008**  
*Skin Irrit. 2 H315 Causes skin irritation.*  
*Eye Irrit. 2 H319 Causes serious eye irritation.*
  - **2.2 Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008**  
*As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation 1272/2008.*  
*The product is classified and labelled according to the CLP regulation.*
  - **Hazard pictograms**
- 

GHS07
- **Signal word** *Warning*
  - **Hazard statements**  
*H315 Causes skin irritation.*  
*H319 Causes serious eye irritation.*
  - **Precautionary statements**

|                       |   |
|-----------------------|---|
| <i>P280</i>           | <i>Wear protective gloves/protective clothing/eye protection/face protection.</i>   |
| <i>P264</i>           | <i>Wash thoroughly after handling.</i>  |
| <i>P305+P351+P338</i> | <i>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</i> |
| <i>P321</i>           | <i>Specific treatment (see on this label).</i>  |
| <i>P332+P313</i>      | <i>If skin irritation occurs: Get medical advice/attention.</i>   |
| <i>P337+P313</i>      | <i>If eye irritation persists: Get medical advice/attention.</i>  |

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- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

## SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture consisting of the following components.

### · **Dangerous components:**

|           |                           |   |         |
|-----------|---------------------------|---|---------|
| 9003-42-3 | Poly (ethyl methacrylate) | ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319 | 50-100% |
|-----------|---------------------------|---|---------|

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

## SECTION 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.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Information for doctor** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

## SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents** Water with full jet.
- **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.

## SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Particular danger of slipping on leaked/spilled product.  
Avoid formation of dust.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling  
See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

### SECTION 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:** Keep receptacle tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 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**  
Immediately remove all soiled and contaminated clothing  
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

- **Material of gloves**

Nitrile rubber, NBR

Recommended thickness of the material:  $\geq 0.12$  mmPermeation: Level  $\geq 1$ 

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 through time has to be found out by the manufacturer of the protective gloves and has to be observed.

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· **Eye protection:**

Tightly sealed goggles.

· **Body protection:** Protective work clothing.

### SECTION 9: Physical and chemical properties

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

|                           |                 |
|---------------------------|-----------------|
| · <b>Form:</b>            | Solid.          |
| · <b>Colour:</b>          | Colourless      |
| · <b>Odour:</b>           | Characteristic  |
| · <b>Odour threshold:</b> | Not determined. |

· **pH-value:** Not applicable.· **Change in condition**

|                                       |               |
|---------------------------------------|---------------|
| · <b>Melting point/Melting range:</b> | > 210 °C      |
| · <b>Boiling point/Boiling range:</b> | 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:**

|                 |                 |
|-----------------|-----------------|
| · <b>Lower:</b> | Not determined. |
| · <b>Upper:</b> | Not determined. |

· **Vapour pressure:** Not applicable.

|                            |                       |
|----------------------------|-----------------------|
| · <b>Density at 20 °C:</b> | 1.1 g/cm <sup>3</sup> |
| · <b>Relative density</b>  | Not determined.       |
| · <b>Vapour density</b>    | Not applicable.       |
| · <b>Evaporation rate</b>  | Not applicable.       |

· **Solubility in / Miscibility with**· **Water:** Insoluble· **Partition coefficient (n-octanol/water):** Not determined.· **Viscosity:**

|                     |                 |
|---------------------|-----------------|
| · <b>dynamic:</b>   | Not applicable. |
| · <b>kinematic:</b> | Not applicable. |

· **Solvent content:**· **Organic solvents:** 0.0 %· **Solids content:** 100.0 %

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· **9.2 Other information** No further relevant information available.

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **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

**SECTION 11: Toxicological information**

- **11.1 Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritating effect.
- **Sensitisation:** No sensitising effects known.
- **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

**SECTION 12: Ecological information**

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **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.

**SECTION 13: Disposal considerations**

- **13.1 Waste treatment methods**
- **Recommendation**  
Can be disposed of with household garbage after consulting with the waste disposal facility operator and the pertinent authorities and adhering to the necessary technical regulations.

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

|                                   |
|-----------------------------------|
| · <b>European waste catalogue</b> |
|-----------------------------------|

|           |  |
|-----------|--|
| 18 01 06* | chemicals consisting of or containing dangerous substances |
|-----------|--|

|                               |
|-------------------------------|
| · <b>Uncleaned packaging:</b> |
|-------------------------------|

|   |
|---|
| · <b>Recommendation:</b> Disposal must be made according to official regulations. |
|---|

### SECTION 14: Transport information

|                         |  |
|-------------------------|--|
| · <b>14.1 UN-Number</b> |  |
|-------------------------|--|

|                               |      |
|-------------------------------|------|
| · <b>ADR, ADN, IMDG, IATA</b> | Void |
|-------------------------------|------|

|                                       |  |
|---------------------------------------|--|
| · <b>14.2 UN proper shipping name</b> |  |
|---------------------------------------|--|

|                               |      |
|-------------------------------|------|
| · <b>ADR, ADN, IMDG, IATA</b> | Void |
|-------------------------------|------|

|  |  |
|--|--|
| · <b>14.3 Transport hazard class(es)</b> |  |
|--|--|

|                               |  |
|-------------------------------|--|
| · <b>ADR, ADN, IMDG, IATA</b> |  |
|-------------------------------|--|

|                |      |
|----------------|------|
| · <b>Class</b> | Void |
|----------------|------|

|                             |  |
|-----------------------------|--|
| · <b>14.4 Packing group</b> |  |
|-----------------------------|--|

|                          |      |
|--------------------------|------|
| · <b>ADR, IMDG, IATA</b> | Void |
|--------------------------|------|

|                                      |  |
|--------------------------------------|--|
| · <b>14.5 Environmental hazards:</b> |  |
|--------------------------------------|--|

|                            |    |
|----------------------------|----|
| · <b>Marine pollutant:</b> | No |
|----------------------------|----|

|  |  |
|--|--|
| · <b>14.6 Special precautions for user</b> |  |
|--|--|

|                 |
|-----------------|
| Not applicable. |
|-----------------|

|   |  |
|---|--|
| · <b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> |  |
|---|--|

|                 |
|-----------------|
| Not applicable. |
|-----------------|

|                                 |  |
|---------------------------------|--|
| · <b>UN "Model Regulation":</b> |  |
|---------------------------------|--|

|   |
|---|
| - |
|---|

### SECTION 15: Regulatory information

|  |
|--|
| · <b>15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture</b> |
|--|

|  |
|--|
| No further relevant information available. |
|--|

|  |
|--|
| · <b>15.2 Chemical safety assessment:</b> A Chemical Safety Assessment has not been carried out. |
|--|

### SECTION 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.

|                           |
|---------------------------|
| · <b>Relevant phrases</b> |
|---------------------------|

|                              |
|------------------------------|
| H315 Causes skin irritation. |
|------------------------------|

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*H319 Causes serious eye irritation.*

- **Department issuing MSDS:** Analytical Research
- **Contact:** HotLine for urgent technical support: +49-7531-583-350

· **Abbreviations and acronyms:**

*ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)*

*IMDG: International Maritime Code for Dangerous Goods*

*IATA: International Air Transport Association*

*GHS: Globally Harmonised System of Classification and Labelling of Chemicals*

*EINECS: European Inventory of Existing Commercial Chemical Substances*

*ELINCS: European List of Notified Chemical Substances*

*CAS: Chemical Abstracts Service (division of the American Chemical Society)*

*Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2*

*Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2*

- **\* Data compared to the previous version altered.**

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

- **1.1 Product identifier**
- **Trade name:** *Visco-Gel Lubricant*
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** *Impression material*
- **Uses advised against** *No further relevant information available.*
- **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)*

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
*The product is not classified according to the CLP regulation.*
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
*As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation 1272/2008.*
- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

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

- **3.2 Chemical characterisation: Mixtures**
- **Description:** *Mixture of substances listed below with nonhazardous additions.*
- **Dangerous components:** *Void*
- **Additional information** *For the wording of the listed risk phrases refer to section 16.*

**SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
- **General information** *No special measures required.*
- **After inhalation** *Supply fresh air; consult doctor in case of complaints.*

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- **After skin contact**  
If skin irritation continues, consult a doctor.  
Immediately wash with water and soap and rinse thoroughly.
- **After eye contact** Rinse opened eye for several minutes under running water.
- **After swallowing** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Information for doctor** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

**SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
- **Suitable extinguishing agents**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents** Water with full jet.
- **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.

**SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 Reference to other sections**  
No dangerous substances are released.  
See Section 7 for information on safe handling  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

**SECTION 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:** Store away from oxidising agents.
- **Further information about storage conditions:** Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

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

- **Additional information about design of technical facilities:** No further data; see item 7.

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**Trade name: Visco-Gel Lubricant**

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- **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.

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

- **Material of gloves**

Nitrile rubber, NBR

Recommended thickness of the material:  $\geq 0.35$  mm

Permeation: Level  $\geq 6$

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 through 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.

## SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

**Form:** Oily

**Colour:** Colourless

- **Odour:** Pleasant

- **Odour threshold:** Not determined.

- **pH-value:** Not determined.

- **Change in condition**

**Melting point/Melting range:** undetermined

**Boiling point/Boiling range:** Undetermined.

- **Flash point:** Not applicable

- **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:** 0.5 Vol %

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|   |  |
|---|--|
| <b>Upper:</b>                                     | 4.5 Vol %                                  |
| · <b>Vapour pressure at 20 °C:</b>                | 0.1 hPa                                    |
| · <b>Density:</b>                                 | Not determined                             |
| · <b>Relative density</b>                         | Not determined.                            |
| · <b>Vapour density</b>                           | Not determined.                            |
| · <b>Evaporation rate</b>                         | Not determined.                            |
| · <b>Solubility in / Miscibility with Water:</b>  | Not miscible or difficult to mix           |
| · <b>Partition coefficient (n-octanol/water):</b> | Not determined.                            |
| · <b>Viscosity:</b>                               |  |
| <b>dynamic:</b>                                   | Not determined.                            |
| <b>kinematic:</b>                                 | Not determined.                            |
| · <b>Solvent content:</b>                         |  |
| <b>Organic solvents:</b>                          | 0.0 %                                      |
| · <b>9.2 Other information</b>                    | No further relevant information available. |

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **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

**SECTION 11: Toxicological information**

- **11.1 Information on toxicological effects**
- **Acute toxicity:**

· **LD/LC50 values relevant for classification:**

**ATE (Acute Toxicity Estimates)**

|        |      |            |
|--------|------|------------|
| Dermal | LD50 | 3027 mg/kg |
|--------|------|------------|

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitisation:** No sensitising effects known.
- **Additional toxicological information:**

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

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### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **Other information:** The product is difficultly biodegradable.
- **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.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
  - **Recommendation** Smaller quantities can be disposed of with household waste.
- |                                   |  |
|-----------------------------------|--|
| · <b>European waste catalogue</b> |  |
| 18 01 07                          | chemicals other than those mentioned in 18 01 06 |
- **Uncleaned packaging:**
  - **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

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

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**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**SECTION 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.*

- **Department issuing MSDS:** Analytical Research
- **Contact:** HotLine for urgent technical support: +49-7531-583-350
- **Abbreviations and acronyms:**

*ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)*

*IMDG: International Maritime Code for Dangerous Goods*

*IATA: International Air Transport Association*

*GHS: Globally Harmonised System of Classification and Labelling of Chemicals*

*EINECS: European Inventory of Existing Commercial Chemical Substances*

*ELINCS: European List of Notified Chemical Substances*

*CAS: Chemical Abstracts Service (division of the American Chemical Society)*

*LC50: Lethal concentration, 50 percent*

*LD50: Lethal dose, 50 percent*

- **\* Data compared to the previous version altered.**

GB