Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 16.07.2015 *Version number 4* *Revision: 16.07.2015*

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

· **1.1 Product identifier**

· **Trade name: Guttapercha Points**
· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
· **Application of the substance / the mixture** root canal filling 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**
Aquatic Acute 1 H400 Very toxic to aquatic life.
Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.

· **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**

GHS09

· **Signal word** Warning
· **Hazard statements**
H410 Very toxic to aquatic life with long lasting effects.
· **Precautionary statements**
P273 Avoid release to the environment.
P391 Collect spillage.
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.

(Contd. on page 2)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 16.07.2015 *Version number 4* *Revision: 16.07.2015*

Trade name: Guttapercha Points

(Contd. of page 1)

· **Dangerous components:**

CAS: 1314-13-2 EINECS: 215-222-5	zinc oxide	Aquatic Acute 1, H400; Aquatic Chronic 1, H410	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**
· **General information** No special measures required.
· **After inhalation** Void
· **After skin contact** Void
· **After eye contact** Void
· **After swallowing** Void
· **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**
CO2, 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** No further relevant information available.
· **5.3 Advice for firefighters**
· **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
· **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.
· **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** 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.

(Contd. on page 3)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 16.07.2015 *Version number 4* *Revision: 16.07.2015*

Trade name: Guttapercha Points

(Contd. of page 2)

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*** *Wash hands before breaks and at the end of work.*
· ***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:*** *Not required.*
· ***Body protection:*** *Protective work clothing.*

SECTION 9: Physical and chemical properties

· ***9.1 Information on basic physical and chemical properties***	
· ***General Information***	
· ***Appearance:***	
Form:	*Solid.*
Colour:	*According to product specification*
· ***Odour:***	*Odourless*
· ***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.*

(Contd. on page 4)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 16.07.2015 *Version number 4* *Revision: 16.07.2015*

Trade name: Guttapercha Points

(Contd. of page 3)

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/water):**	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.

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:**		
1314-13-2 zinc oxide		
Oral	LD50	>5000 mg/kg (rat)

· **Primary irritant effect:**
· **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
· **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
· **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
· **Carcinogenicity** Based on available data, the classification criteria are not met.
· **Reproductive toxicity** Based on available data, the classification criteria are not met.
· **STOT-single exposure** Based on available data, the classification criteria are not met.
· **STOT-repeated exposure** Based on available data, the classification criteria are not met.
· **Aspiration hazard** Based on available data, the classification criteria are not met.

(Contd. on page 5)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 16.07.2015 *Version number 4* *Revision: 16.07.2015*

Trade name: Guttapercha Points

(Contd. of page 4)

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
1314-13-2 zinc oxide	
EC50/48h	0.098 mg/L (daphnia magna)
LC50/96h	1.1 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.
· **Ecotoxical effects:**
· **Remark:** Very toxic for fish
· **Additional ecological information:**
· **General notes:**
Do not allow product to reach ground water, water course or sewage system.
Also poisonous for fish and plankton in water bodies.
Very toxic for aquatic organisms
· **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**	UN3077
· **14.2 UN proper shipping name**	
· **ADR**	3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)
· **IMDG**	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), MARINE POLLUTANT
· **IATA**	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)

(Contd. on page 6)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 16.07.2015 *Version number 4* *Revision: 16.07.2015*

Trade name: Guttapercha Points

(Contd. of page 5)

· **14.3 Transport hazard class(es)**

· **ADR**

· **Class**	9 (M7) Miscellaneous dangerous substances and articles.
· **Label**	9

· **IMDG, IATA**

· **Class**	9 Miscellaneous dangerous substances and articles.
· **Label**	9

· **14.4 Packing group**	
· **ADR, IMDG, IATA**	III
· **14.5 Environmental hazards:**	
· **Marine pollutant:**	Yes Symbol (fish and tree)
· **Special marking (ADR):**	Symbol (fish and tree)
· **Special marking (IATA):**	Symbol (fish and tree)
· **14.6 Special precautions for user**	Warning: Miscellaneous dangerous substances and articles.
· **Danger code (Kemler):**	90
· **EMS Number:**	F-A,S-F
· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **Transport/Additional information:**	
· **ADR**	
· **Limited quantities (LQ)**	5 kg
· **Excepted quantities (EQ)**	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· **Transport category**	3
· **Tunnel restriction code**	E
· **Remarks:**	Exemption according to ADR special provision 375: This substance is not subject to the other provisions of the ADR if packed in net quantities of 5L or 5kg per individual or inner packaging, provided that sub-sections 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8 are complied with.
· **IMDG**	
· **Limited quantities (LQ)**	5 kg
· **Excepted quantities (EQ)**	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· **UN "Model Regulation":**	UN3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), 9, III

GB

(Contd. on page 7)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 16.07.2015 *Version number 4* *Revision: 16.07.2015*

Trade name: Guttapercha Points

(Contd. of page 6)

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.

· ***Relevant phrases***
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

· ***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
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1
· **** Data compared to the previous version altered.***