SAFETY DATA SHEETS

This SDS packet was issued with item: 071729516

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

020170109 071733203

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

070503151 070504811 070509133 070509141 071127372 071127406 071127539 071725704 071725712 071725720 071725738 071725746 071725753 071725761 071725779 071725787 071725795 071725803 071725811 071725829 071725837 071725845 071729466 071729474 071729482 071729490 071729508 071729524 071729532 071729540 071729664 071729672 071729680 071729698 071729706 071729714 071729722 071729730 071729748 071729755 071729763 071729771 071729797 071729805 071729813 071729821 071733153 071733161 071733179 071733187 071733195 071733211 071733229 071733237 071733245 071733252 071733260 071733278 071733286 071733294 071733302 071733310

Printing date 04/28/2011

Version number 1

Revision: 04/26/2011

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

· Product identifier

· Trade name: Guttapercha Points

• Relevant identified uses of the substance or mixture and uses advised against • Application of the substance / the preparation root canal filling material

• 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

Supplier for CANADA: Dentsply Canada 161 Vinyl Court Woodbridge, ON L4L4A3

Tel.: (905) 851 6060 or 1-800-263-1437 *Fax*: (905) 851-9809

· Further information obtainable from:

- Departement Analytical Research / Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets
- Emergency telephone number: +49-(0)7531-583-0

2 Composition/information on ingredients

· Chemical characterization: Mixtures

• Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:

1314-13-2 zinc oxide

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

3 Hazards identification

- · 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.

· Label elements

· Labelling according to EU guidelines:

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

(Contd. on page 2)

N R50/53 50-100%

Printing date 04/28/2011

Version number 1

Revision: 04/26/2011

Trade name: Guttapercha Points

(Contd. of page 1)

· 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.

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

4 First aid measures

- · Description of first aid measures
- After inhalation Void
- · After skin contact Void
- After eye contact Void
- · After swallowing Void

5 Firefighting measures

- · Extinguishing media
- · Suitable extinguishing agents
- CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- · Advice for firefighters
- · Protective equipment: Wear self-contained respiratory protective device

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions: Inform respective authorities in case of seepage into water course or sewage system.
- Methods and material for containment and cleaning up: Pick up mechanically.
- **Reference to other sections** See Section 7 for information on safe handling See Section 8 for information on personal protection.
- See Section 8 for information on personal protection equipment.
- See Section 13 for disposal information.

7 Handling and storage

- · Handling Product is intended for dental use only.
- · Precautions for safe handling Observe normal care for working with chemicals.
- · Information about fire and explosion protection: No special measures required.
- · 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.

(Contd. on page 3)

CDN

Printing date 04/28/2011

Version number 1

Revision: 04/26/2011

Trade name: Guttapercha Points

(Contd. of page 2)

• Further information about storage conditions: Store in cool, dry conditions in well sealed receptacles.

8 Exposure controls/personal protection

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

· Control parameters

· Ingredients with limit values that require monitoring at the workplace:

1314-13-2 zinc oxide

TLV Short-term value: 10 mg/m3 Long-term value: 5 mg/m3

· Additional information: The lists valid during the making were used as basis.

- · 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.

· Respiratory protection: Not required.

· 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.

9 Physical and chemical properties

• General Information		
· Appearance:	~	
Form:	Solid.	
Colour:	According to product specification	
· Odour:	Odourless	
 Change in condition Melting point/Melting rang Boiling point/Boiling rang 		
· Flash point:	Not applicable	
	Not applicable Product is not selfigniting.	
· Flash point: · Self-igniting: · Danger of explosion:	**	

Printing date 04/28/2011

Version number 1

Revision: 04/26/2011

Trade name: Guttapercha Points

(Contd. of page 3)

• Solubility in / Miscibility with Water:

10 Stability and reactivity

- · Reactivity
- · Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- Possibility of hazardous reactions No dangerous reactions known

Insoluble

 $\cdot \textit{Hazardous decomposition products: No dangerous decomposition products known}$

11 Toxicological information

- · 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

- · Toxicity
- · Acquatic toxicity: No further relevant information available.
- · Ecotoxical effects:
- *Remark:* Very toxic for fish
- \cdot Additional ecological information:
- · General notes:
- Also poisonous for fish and plankton in water bodies.
- Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water.
- Very toxic for aquatic organisms
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation



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

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

(Contd. on page 5)

CDN

Printing date 04/28/2011

Version number 1

Revision: 04/26/2011

Trade name: Guttapercha Points

(Contd. of page 4)

TDG (Transport dange	rous goods):
• TDG class:	9 (M7) Miscellaneous dangerous substances and articles.
· Danger code (Kemler):	
· UN-Number:	3077
• Packaging group:	III
· Hazard label	9
Special marking:	Symbol (fish and tree)
• UN proper shipping na • Tunnel restriction code	
• Maritime transport IM	DG:
· IMDG Class:	9
· UN Number:	3077
· Label	9
• Packaging group:	
• EMS Number:	F-A,S-F
• Marine pollutant:	Yes
Duonau chinning name	Symbol (fish and tree) ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)
· Air transport ICAO-TI	and IATA-DGR:
· ICAO/IATA Class:	9
· UN/ID Number:	3077
· Label	9
• Special marking:	Symbol (fish and tree)
• Packaging group:	III
• Proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)
• Special precautions for	user Warning: Miscellaneous dangerous substances and articles.

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture

- · National regulations
- Waterhazard class: Water hazard class 2 (Self-assessment): hazardous for water.
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

(Contd. on page 6)

CDN

Printing date 04/28/2011

Version number 1

Revision: 04/26/2011

Trade name: Guttapercha Points

(Contd. of page 5)

CDN

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: +49-7531-583-333

Printing date 31.05.2017

Version number 6

Revision: 31.05.2017

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.
- \cdot 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@dentsplysirona.com

- · Further information obtainable from:
- Departement 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

 \cdot 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
- *The product is classified and labelled according to the CLP regulation. Hazard pictograms*



- · 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. • *Additional information:*

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.

- · 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)

Printing date 31.05.2017

Version number 6

Revision: 31.05.2017

Trade name: Guttapercha Points

		(C	ontd. of page 1)
· Dangerous compon	ents:		
CAS: 1314-13-2	zinc oxide	Aquatic Acute 1, H400; Aquatic Chronic 1, H410	50-100%
EINECS: 215-222-5	5	• •	
Additional informa	tion For the wording	a of the listed has and physics refer to section 16	

• Additional information For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

• 4.1 Description of first aid measures

· After inhalation not applicable

· After skin contact not applicable

- · After eye contact not applicable
- · After swallowing not appliable
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Information for doctor No further relevant information available.
- \cdot 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:
- Dispose contaminated material as waste according to item 13.
- **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)

Printing date 31.05.2017

Version number 6

Revision: 31.05.2017

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: Not required.
- · Material of gloves not applicable
- · Penetration time of glove material not applicable
- · Eye protection: Not required.
- · Body protection: Protective work clothing.

SECTION 9: Physical and chemical properties

	• 9.1 Information	on basic	physical (and chemi	cal properties
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· General Information

•	Appearance:	
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Appearance:	
Form:	Solid.
Colour:	According to product specification
Odour:	Odourless
Odour threshold:	Not determined.
pH-value:	Not applicable.
Change in condition	
Melting point/freezing point:	undetermined
Initial boiling point and boiling range:	Undetermined.
Flash point:	Not applicable
Flammability (solid, gaseous)	Not determined.
Ignition temperature:	Not applicable
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	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/water:	Not determined.

(Contd. on page 4) GB

Printing date 31.05.2017

Version number 6

Revision: 31.05.2017

Trade name: Guttapercha Points

		(Contd. of page 3
· Viscosity:		
dynamic:	Not applicable.	
kinematic:	Not applicable.	
· Solvent content:		
Organic solvents:	0.0 %	
Solids content:	100 %	
· 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.

 \cdot 10.3 Possibility of hazardous reactions No dangerous reactions known

 \cdot 10.4 Conditions to avoid No further relevant information available.

 \cdot 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 Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

CAS: 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.

SECTION 12: Ecological information

· 12.1 Toxicity

• Aquatic toxicity:

CAS: 1314-13-2 zinc oxide

LC50/96h 1.1 mg/l (Fish acute toxicity study)

EC50/48h 0.098 mg/L (daphnia magna)

· 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

(Contd. on page 5)

Printing date 31.05.2017

Version number 6

Revision: 31.05.2017

(Contd. of page 4)

Trade name: Guttapercha Points

· 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.
- $\cdot vPvB$: Not applicable.
- \cdot 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 hazardous substances
HP 14	Ecotoxic

· 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 SUBSTANCI
	SOLID, N.O.S. (zinc oxide)
·IMDG	ENVIRONMENTALLY HAZARDOUS SUBSTANCI
	SOLID, N.O.S. (zinc oxide), MARINE POLLUTANT
·IATA	ENVIRONMENTALLY HAZARDOUS SUBSTANCI SOLID, N.O.S. (zinc oxide)
· 14.3 Transport hazard class(es)	
· ADR	
· Class	9 (M7) Miscellaneous dangerous substances and articles.
· Label	9
· IMDG, IATA	
V V	
Class Label	9 Miscellaneous dangerous substances and articles. 9

Printing date 31.05.2017

Version number 6

Revision: 31.05.2017

Trade name: Guttapercha Points

	(Contd. of page
14.4 Packing group ADR, IMDG, IATA	111
14.5 Environmental hazards:	Product contains environmentally hazardous substances zinc oxide
Marine pollutant:	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 an articles.
Danger code (Kemler):	90
EMS Number:	F-A,S-F
Stowage Category	Α
Stowage Code	SW23 When transported in BK3 bulk container, se 7.6.2.12 and 7.7.3.9.
14.7 Transport in bulk according to Ann Marpol and the IBC Code	ex II of Not applicable.
Transport/Additional information:	
ADR	
Limited quantities (LQ)	5 kg
Excepted quantities (EQ)	Code: El
	Maximum net quantity per inner packaging: 30 g
T	Maximum net quantity per outer packaging: 1000 g
Transport category Remarks:	3 Encoder the second in the ADD encoded encoded in 275.
Kemarks:	Exemption according to ADR special provision 375: This substance is not subject to the other provisions of th
	ADR if packed in net quantities of 5L or 5kg per individu
	or inner packaging, provided that sub-sections 4.1.1.
	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 $(\widetilde{E}Q)$	Code: El
	Maximum net quantity per inner packaging: 30 g
	Maximum net quantity per outer packaging: 1000 g
UN ''Model Regulation'':	UN 3077 ENVIRONMENTALLY HAZARDOU
	SUBSTANCE, SOLID, N.O.S. (ZINC OXIDE), 9, III

SECTION 15: Regulatory information

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

· Directive 2012/18/EU

- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Seveso category E1 Hazardous to the Aquatic Environment
- \cdot Qualifying quantity (tonnes) for the application of lower-tier requirements 100 t
- \cdot Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t
- 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.

(Contd. on page 7)

Printing date 31.05.2017

Version number 6

Revision: 31.05.2017

Trade name: Guttapercha Points

For quantities of material typically used in clinical practice, information a of the product is given in the DFU.	(Contd. of page 6) necessary for safe use and storage
Relevant phrases H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.	
Department issuing SDS: Research & Development Contact: HotLine for urgent technical support: +49-7531-583-350	
Abbreviations and acronyms: ADR: Accord européen sur le transport des marchandises dangereuses par Route (Europea Carriage of Dangerous Goods by Road)	an Agreement concerning the International
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 - acute aquatic hazard – Category 1	
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Categ * Data compared to the previous version altered.	ory 1
	G