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I 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

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

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

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N R50/53 | 50-100%

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· 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 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.

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· 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

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

Form: Solid.

Colour: According to product specification

· Odour: Odourless

· Change in condition

Melting point/Melting range: undetermined Boiling point/Boiling range: undetermined

· Flash point: Not applicable

· Self-igniting: Product is not selfigniting.

• Danger of explosion: Product does not present an explosion hazard.

· **Density:** Not determined

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· Solubility in / Miscibility with

Water: Insoluble

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
- · 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
- · 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.

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14 Transport information

· TDG (Transport dangerous goods):



• TDG class: 9 (M7) Miscellaneous dangerous substances and articles.

Danger code (Kemler): 90
UN-Number: 3077
Packaging group: III
Hazard label 9

· **Special marking:** Symbol (fish and tree)

· UN proper shipping name: · Tunnel restriction code E

· Maritime transport IMDG:



· IMDG Class: 9
· UN Number: 3077
· Label 9
· Packaging group: III
· EMS Number: F-A,S-F
· Marine pollutant: Yes

Symbol (fish and tree)

· Proper shipping name: 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.
- · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.

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.

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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

CDN