



Document Detail

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Approval

<u>Owner Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
0170-QA/RA Reviewer TDS-QA/RA Reviewer	Terri Stanton	23-Apr-2021 1:07 pm	GMT
1000- R&D Technical lead ENDODONTICS R&D Technical lead	Vince Shotton	21-Apr-2021 7:38 pm	GMT
1000- Product Compliance Manager ENDODONTICS Product Compliance Manager	Allison Schwarz	21-Apr-2021 8:15 pm	GMT
1000- R&D Platform Lead ENDODONTICS R&D Platform Lead	Kevin Wilkinson	22-Apr-2021 8:44 pm	GMT
1000- Marketing Product Manager ENDODONTICS Marketing Product Manager	Jean-Marie Guillemin	22-Apr-2021 5:45 am	GMT

Dentsply Sirona Endodontics

Safety Data Sheet

Conforms with OSHA Hazard Communication Standard (CFR 29 1910.1200) HazCom 2012

According to 1907/2006/EC, Article 31

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SECTION 1: Identification

1.1 Product identifier: Injection Molded Gutta Percha Master Cones

Trade name: ProTaper Gold®, WaveOne Gold®, ProTaper Next®, TruNatomy™, ConformFit™, ProTaper Ultimate™, ProTaper® Universal (US Only), TRUShape® (US Only) Vortex Blue® (US Only)

1.2 Relevant identified uses of the substance or mixture

For Dental use only.

Application of the substance / the preparation

Dental root canal filling material

1.3 Details of the supplier

U.S.A and Canada contact:

DENTSPLY Tulsa Dental Specialties

608 Rolling Hills Drive

Johnson City, TN 37604

Information department:

1 (800) 662-1202

Outside U.S.A and Canada contact:

Maillefer Instruments Holding Sàrl

Chemin du Verger 3

1338 Ballaigues, Switzerland

Information department:

+41 (0)21 843 92 92

1.4 Emergency telephone number: Chemtrec (800) -262-8200

Email address: Chemtrec@chemtrec.com

SECTION 2: Hazard(s) Identification

2.1 Classification of the substance or mixture

Classification according to Directive 1272/2008/EEC (GHS/CLP)

Classification of the substance or mixture

Aquatic 1 H410 Very toxic to aquatic life with long lasting effects

H320 Causes eye irritation.

Information concerning hazards for human and environment:

The product must be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" and the GHS-regulation in the latest valid version.

Classification system:

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

2.2 Label elements

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GHS label elements the product is classified and labeled according to the Globally Harmonized System (GHS).

Hazard pictograms:



G09

Signal word: Warning

Hazardous Statement:

H320 Causes eye irritation

H410 Very toxic to aquatic life with long lasting effects

Precautionary Statements:

P102 Keep out of reach of children

P273 Avoid release to the environment

P281 Use personal protective equipment as required

P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.

P332 Take off contaminated clothing.

P391 Dispose of contents/container in accordance with local/regional/national/international regulations.

P410 Protect from sunlight

P411 Store at temperatures not exceeding 37°C/99°F

P501 Disposal of contents/ container as hazardous or special waste in accordance with applicable law

Hazard-determining components of labelling:

Zinc Oxide

Special labelling of certain preparations:

NA

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable

SECTION 3: Composition/Information on Ingredients

3.1 Chemical characterization: Substance

N/A

3.2 Chemical characterization: Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

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Dangerous components:		
CAS: 1314-13-2	Zinc Oxide	45 – 55%
EC# 215-222-5	 Very toxic to aquatic life 1, H410;	

Nonhazardous components:		
CAS: 9000-32-2	Gutta Percha	20 – 30%

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 notes

After inhalation NA

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 Not hazardous if ingesting small quantity. Product is to be handed by professional dentist only.

Aspiration is avoided using rubber dam on the patient during application.

4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

SECTION 5: Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing agents

Smothering agents, or other commonly used fire extinguishing methods

5.2 Special hazards arising from the substance or mixture

 NA

5.3 Advice for firefighters

 NA

Protective equipment: Eyes/Face Shield, Gloves, Respiratory, Thermal Body Suit

SECTION 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures Wear protective clothing.

6.2 Environmental precautions:

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

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

6.3 Methods and material for containment and cleaning up:

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

Ensure adequate ventilation.

6.4 Reference to other sections

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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

Use normal care when working with chemicals. Eye, face and hand protection Wash hands after use.

Advice on safe Handling Product is intended for dental use only. Additional information you can get from technical data sheet.

Information about fire - and explosion protection: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

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: Store in cool, dry conditions in well-sealed receptacles. Avoid exposure to direct sunlight / UV light and heat over 38°C.

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

Specific Eye/face Protection: Safety goggles are recommended.

Specific Skin Protection: Impervious gloves are recommended.

General protective and hygienic measures

Keep away from foodstuffs, beverages and feed.

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

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

Respiratory protection: Not necessary if room is well-ventilated.

Protection of hands:



Protective gloves.

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The glove material must 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: ≥ 0.38 mm

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 cannot be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

NA

Eye protection:

Safety glasses



Tightly sealed goggles

SECTION 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

General Information	
Appearance:	
• Form	Uniformly cylindrical shape
• Color	Pink
Odor	NA
Odor threshold	NA
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	Not determined

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• Upper	Not determined
Vapor pressure	Not determined
Density	Not determined
Relative density	Not determined
Vapor density	Not determined
Evaporation rate	Not determined
Solubility in / Miscibility with water	Water - No Ether - Yes
Partition coefficient (n-octanol/Water)	NA
Viscosity	
• dynamic	Not determined
• kinematic	Not determined
Solvent content:	
• Organic solvents	0,0 %

9.2 Other information

No further relevant information available

SECTION 10: Stability and Reactivity

10.1 Reactivity This is a stable compound that will not degrade to unstable products or hazardous materials.

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 Natural light, excessive heat and humidity (Stability)

10.5 Incompatible materials: Strong oxidizing agents

10.6 Hazardous decomposition products: Carbon Monoxide, Carbon Dioxide, Hydrocarbon & Zinc. Fumes when heated to decomposition.

SECTION 11: Toxicological Information

Information on toxicological effects

Acute toxicity

LD/LC50 values relevant for classification: None		
1314-13-2 Zinc Oxide		
Oral	LD50	None
Dermal	LD50	None
9000-32-2 Gutta Percha		
Oral	LD50	None

Irritant effect:

skin: Irritant to skin

eye: Irritating effect.

Sensitization: Sensitization possible through skin contact.

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The substance or mixture is not classified yet. The substance or mixture contains no mutagen classified substance.

Carcinogenicity

The substance or mixture is not classified yet. The substance or mixture contains no carcinogen classified substance.

Reproductive Toxicity

The substance or mixture is not classified yet. The substance or mixture contains no reprotoxic classified substance.

Specific target organ toxicity - single exposure

The substance or mixture is not classified yet. The substance or mixture contains no target organ classified by single exposure substance.

Specific target organ toxicity - repeated exposure

The substance or mixture is not classified yet. The substance or mixture contains no target organ classified by repeated exposure substance.

Inhalation

The substance or mixture is not classified yet.

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:	
1314-13-2 Zinc Oxide	
EC50/48h	0.098 MG/L (daphnia)
LC50/96h	1.1 mg/L (fish)

12.2 Persistence and degradability No further relevant information available.

12.3 Bio-accumulative potential No further relevant information available.

12.4 Mobility in soil No further relevant information available.

Additional ecological information:

General notes:

Water hazard class 2 (self-assessment): hazardous for water (only applies for Germany)

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

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

Also poisonous for fish and plankton in water bodies.

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

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Recommendation



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

European waste catalogue

18 01 06* chemicals consisting of or containing dangerous substance

Uncleaned packaging: 15 01 10* packaging containing residues of or contaminated by dangerous substances.

Recommendation: Disposal must be made according to official regulations. Completely emptied packaging can be recycled.

SECTION 14: Transport Information

14.1 UN-Number:

3077(Zinc Oxide)

14.2 UN proper shipping name

ADR/RID

3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. 1314-13-2 Zinc Oxide

IMDG / ICAO-TI

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. MARINE POLLUTANT

IATA, DGR

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S 1314-13-2 Zinc Oxide

14.3 Air Transport hazard class(es)

ICAO-TI and IATA-DGR



Class

Label

9

9 (M6) Miscellaneous dangerous substances and articles.

IMDG, IATA



Class

9 Miscellaneous dangerous substances and articles.

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Label	9
14.4 Packing group ADR, IMDG, IATA III substances with low risk	
14.5 Environmental hazards: Product contains environmentally hazardous substances Marine pollutant: Yes Hazard Symbol (environmentally hazardous substances) Special marking (ADR): Hazard Symbol (environmentally hazardous substances) Special marking (IATA): Hazard Symbol (environmentally hazardous substances)	
14.6 Special precautions for user: Warning: Miscellaneous dangerous substances and articles Danger code (Kemler): 90 Environmentally hazardous substance; miscellaneous dangerous substance 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) 5L Transport category 3 Tunnel restriction code E	

SECTION 15: Regulatory Information

15.1 Safety, health and environmental regulations / specific legal regulation for the substance or mixture

National regulation:

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

SECTION 16: Other Information

Data Sources: To the best of our knowledge, the information contained herein is accurate. However, neither above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described, we cannot guarantee that these are the only hazards that exist.

Relevant phrases

H320: Causes eye irritation

H410: Very toxic to aquatic life with long lasting effects

P102: Keep out of reach of children

P273: Avoid release to the environment

P281: Use personal protective equipment as required

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P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing

P332: If skin irritation occurs: consult Physician

P391: Collect spillage.

P410: Protect from sunlight

P411: Store at temperatures not exceeding 37°C/99°F

P501: Disposal of contents/ container as hazardous or special waste in accordance with applicable law.

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