SAFETY DATA SHEETS

This SDS packet was issued with item:

073780657

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

070430603

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).

070430496 070430587 070430678 073779907 073779915 073779923 073779931 073779949 073779956 073779964
073779972 073779980 073779998 073780004 073780012 073780020 073780152 073780160 073780178 073780186
073780194 073780202 073780210 073780228 073780236 073780244 073780251 073780269 073780277 073780285
073780293 073780533 073780541 073780558 073780566 073780574 073780582 073780590 073780608 073780616
073780624 073780632 073780640 073780665 073780673 073780939 073780947 073780954 073780962 073780970
073780988 073780996 073781002 073781010 073781028 073781036 073781044 073781051 073781069 073781077
073781085 073781093 073781101 073781119 073781184 073781192 073781200 073781218 073781226 073781234
073781242 073781259 073781267 073781275 073782117 073782125 073782133 073782141 073782158 073782166
073782174 073782257 073782323 073782331 073782372 073782380 073782398 073782406 073782414 073782422
073782430 073782448 073782455 073782463 073782471 073782489 073782497 073782505 073795002 073795010
073795028 073795036 073795044 073795051 073795069 073795077 073795150 073795168 073795176 073795184
073795192 073795200 073795218 073795226 073795234 073795242 073795259 073795267 073795275 073795309
073795317 073795325 073796091 073796653 073796661 073796679 073796687 073796695 073796703 073796711
073796729 073796737 073796745 073796752 073796760 073796778 073796786 073796794 073802501 073802519
073802527 073802535 073802543 073802550 073802568 073802576 073802584 073802592 073802600 073802618
073802626 073802634 073802642 073802659 073802667 073802675 073802683 073802691 073802709 073802717

1. **Identification of the Substance/Preparation and of the Company/Undertakings**

Product Details:
Trade Name: Gutta Percha Points
Manufacturer:

Coltène/Whaledent Inc.
235 Ascot Parkway
Cuyahoga Falls, OH 44223 / USA
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+1 330 916 8800
Fax +1 330 916 7077
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Coltène/Whaledent GmbH + Co. KG EC REP
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Tel. +49 (0) 7345 805 0
Fax +49 (0) 7345 805 201
info@coltenewhaledent.de

Emergency Contact Numbers:
USA & Canada: +1 800 535 5053
Main Phone Number: +1 330 916 8800

2. **Hazard Identification**

Hazard Designation: Not hazardous.
Information Pertaining to Particular Dangers for Man and Environment: None.
Classification is in Line with EC Directive 1999:45/EC: N.A.

3. **Composition/Information on Ingredients**

Chemical Characterization: Paper Points
Hazardous Components:

Chemical Name	Weight %	Index, R/S Phrases
None		
NON Hazardous Components		
USP Zinc Oxide (CAS# 1314-13-2)	< 70%	
Barium Sulphate (CAS# 7727-43-7)	< 15%	
FD&C Yellow #5	< 1%	

4. **First-Aid Measures**

After Inhalation: N.A.
After Skin Contact: N.A.
After Eye Contact: If scratches or punctures occur, seek medical attention immediately.
After Swallowing: Do not induce vomiting. Material is chemically inert.

5. **Fire-Fighting Measures**

Flammability: Nonflammable **Flash Point: N.A.** **LEL: N.A.** **UEL: N.A.**
Extinguishing Media: Water, CO_2, dry chemical or foam.
Unsuitable Extinguishing Media: None known.
Protective Equipment: Wear NIOSH approved self-contained breathing respirator in positive pressure mode.

6. **Accidental Release Measures**

Personal Precautions: None.
Environmental Precautions: None.
Methods of Cleaning Up: N.A.

7. **Handling and Storage**

Precautions for Safe Handling: Always wear gloves and eye protection. Keep container closed when not in use.
Storage: Keep out of reach of children. Keep container closed.

8. **Exposure Controls/Personal Protection**

Components with Recommended Limits for the Work Place:

CAS No.	Chemical Name	Weight %	Type/Value
None			

Engineering Controls: N.A.
Work/Hygienic Protection: N.A.
Hand/Skin Protection: N.A.
Respiratory Protection: Wear safety mask when shortening or removing post from tooth.
Eye Protection: Wear safety goggles.

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9. **Physical and Chemical Properties**

Appearance: Colored Thermoplastic Cones	Odor: None	Solubility : N.A.
Boiling Point: N.A.	Flash Point: N.A.	Method: N.A.
Flammability: Nonflammable	Autoflammability: N.A.	Density: N.A.
Vapor Pressure: N.A.	Explosive Properties: N.A.	Explosive Limits in Air: N.K.
pH: N.A.	Viscosity: N.A.	Method: N.A.

10. **Stability and Reactivity**

Chemical Stability: Stable.
Conditions to Avoid: N.K.
Materials to Avoid: None.
Hazardous Decomposition Products: CO.

11. **Toxicological Information**

Acute Toxicity: N.A.
Primary Effects to Skin: Not a primary dermal irritant.
Primary Effects to Eyes: Not an ocular irritant.
Primary Effects to Respiratory System: Not an acute inhalation hazard.
Sensitization: N.A.
Additional Toxicological Info: N.A.

12. **Ecological Information**

General Information: N.A.
Classification of Water Endangerment: N.A.

13. **Disposal Considerations**

Product: Not considered a RCRA hazardous waste as identified in Fed. Reg. 40CFR261. If this product cannot be used as directed by the label, contact the local Environmental Control Agency or Agent.

14. **Transportation Information**

DOT Shipping Name:	DOT Hazard Class:	UN-No.: N.A.
Not regulated	Not regulated	
Sea Transport IMDG/GGV Sea	UN. No.: N.A.	EmS-No.: N.A.
Class: N.A.		MFGA-No.: N.A.
Air Transport ICAO-Ti and IATA-DGR	UN. No.: N.A.	
Class: N.A.		

15. **Regulatory Information**

TSCA Inventory Status: This product and/or all of its components are included on the TSCA Inventory of Chemical Substances.
SARA 311/312 Hazard Categories: None.
SARA 302 Extremely Hazardous Substances: None.
SARA 313 Toxic Chemicals:

Chemical Name	CAS No.	Weight %
None		

Classification According to EEC Guidelines: N.A.
Classification According to VBF: N.A.
Canadian Regulations require the inclusion of the following statements under “Regulatory Information”;
“This product has been classified in accordance with the hazard criteria of the controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations.”

16. **Other Information**

Revision Summary: 6/14/04 Changed Address and added EU Rep. 12/5/08 Updated to current EU standards in header and section 3. 12/7/12 – Triennial review, section 2 was “Composition / Information on Ingredients” & section 3 was “Hazard Identification”.

The information and recommendations set forth herein are presented in good faith and are believed to be correct as of the date hereof. Coltène/Whaledent Inc., however, makes no representations as to the completeness of security of this information and supplies it on the condition that the persons receiving same will make their own determination as to its suitability of their purposes prior to use. In no event will Coltène/Whaledent Inc. be responsible for damages of any nature whatsoever resulting from use of or reliance upon information.

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Safety Data Sheet

ANSI Z400.1/Z129.1-2010

Hygenic® Gutta Percha Points

Section 1: PRODUCT AND COMPANY IDENTIFICATION

Product Names: Hygenic Gutta Percha Points (Sized to ADA Spec. #57 (Conventional Shapes)
Hygenic Gutta Percha Points Original Hygenic Spec. (Conventional Shapes)
Hygenic Gutta Percha Points AAE/ISO Spec. (Standardized)
Hygenic SpectraPoint® Gutta Percha Points
Hygenic SpectraPoint® Greater Taper Gutta Percha Points

Product Code(s): See Section 16 for applicable product codes.

Relevant identified uses of the mixture and uses advised against: Gutta Percha is a device made from coagulated sap of certain tropical trees intended to fill the root canal of a tooth. The Gutta Percha is softened by heat and inserted into the root canal, where it hardens as it cools. Intended for use by a licensed physician. Uses advised against: none.

Synonyms: None

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Fax: 1 330 916 7077
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Authorized EC Representative EC REP
Coltène/Whaledent GmbH + Co. KG
Raiffeisenstraße 30
89129 Langenau
Phone: 49 7345 805 0
Fax: 49 7345 805 201
info.de@coltene.com

Emergency Contact Number:
USA & Canada: 1 800 535 5053

Copies of this SDS can be found at www.coltene.com

Section 2: HAZARDS IDENTIFICATION

Appearance: Colored, Thermoplastic Cones (Odorless)

Classification: Not hazardous when used in accordance with the relevant identified uses. Spectrapoints are formed to a specific shape or design during manufacture; have end use function(s) dependent in whole or in part upon their shape or design during end use; and under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees.

PBT/vPvB Assessment: This product does not contain persistent, bioaccumulative and toxic chemicals (PBT's) nor does this product contain any very persistent and very bioaccumulative chemicals (vPvB's).

Section 3: COMPOSITION / INFORMATION ON INGREDIENTS

Substance	CAS	Percent (w/w%)
USP Zinc Oxide	1314-13-2	< 70%
Barium Sulphate	7727-43-7	< 15%
FD&C Yellow #5	-	< 1%

Section 4: FIRST AID MEASURES

Inhalation: Not a likely route of exposure

Eyes: If scratches or punctures occur, seek medical attention immediately.

Skin: Not hazardous to the skin. If you experience an adverse reaction, wash contacted skin with soap and water. If symptoms persist, consult a physician.

Ingestion: Do not induce vomiting. Material is chemically inert.

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Section 5: FIRE FIGHTING MEASURES

Flammability: Nonflammable.

Extinguishing Media: Carbon dioxide, foam and dry chemicals.

Unsuitable Extinguishing Media: None known.

Specific Hazards Arising from the Chemical: None known.

Protective Equipment and Precautions for Firefighters: standard protection for all firefighters stated in this subsection of the SDS text should include self-contained breathing apparatus (SCBA) and full firefighting turn-out gear (Bunker gear).

Section 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment, and Emergency Procedures: use personal protective equipment recommended in Section 8.

Methods for Containment and Clean-up: none noted.

Other Information: none noted

Section 7: HANDLING AND STORAGE

Precautions for Safe Handling: wear gloves and eye protection. Keep container closed when not in use.

Conditions for Safe Storage, Including Incompatibilities: Keep out of reach of children. Keep container closed.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Component Exposure Limits: none

Appropriate Engineering Controls: None required.

Personal Protective Equipment (Eyes and Face): None required.

Personal Protective Equipment (Skin): None required.

Personal Protective Equipment (Respiratory): none required.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Colored, Thermoplastic Cones	Viscosity:	No data
Odor:	None	Odor Threshold:	No data
pH:	No data	Boiling Point:	No data
Melting Point:	No data	Solubility (H_2O):	No data
Specific Gravity:	No data	Evaporation Rate:	No data
Octanol / H_2O Coefficient:	No data	Decomposition Temp:	No data
Molecular Weight:	No data	LFL:	No data
Auto Ignition:	No data	UFL:	No data
Flash Point:	No data	Vapor Pressure:	No data
Vapor Density:	No data	Flammability Class:	No data
VOC:	No data		

Section 10: STABILITY AND REACTIVITY

Reactivity: Not reactive

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Chemical Stability: Chemically stable

Possibility of Hazardous Reactions: None

Conditions to Avoid: None known.

Incompatibility: None

Hazardous Decomposition Products: Carbon Monoxide

Section 11: TOXICOLOGICAL INFORMATION

Likely Routes of Exposure: dermal, eye/skin and ingestion – Gutta Percha is not hazardous

Eye contact: Can cause slight mechanical irritation**.**

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity: Not known.

Persistence / Degradability: Not known

Bioaccumulative Potential: Not known.

Mobility in Soil: Not known.

Other Adverse Effects: None known.

This product does not contain persistent, bioaccumulative and toxic chemicals (PBT's) nor does this product contain any very persistent and very bioaccumulative chemicals (vPvB's).

Section 13: DISPOSAL CONSIDERATIONS

Disposal: Dispose of in accordance with federal, state and local regulations.

Additional Disposal Considerations: None

Section 14: TRANSPORT INFORMATION

Not hazardous for transportation.

Section 15: REGULATORY INFORMATION

SARA Sections 302 and 304: This product does not contain Extremely Hazardous Substances (EHS) and is not subject to emergency planning requirements.

CERCLA: This product does not contain CERCLA Hazardous Substances and is not subject to reporting requirements.

SARA Section 313: Substances within this product are not required to be reported in accordance with SARA 313 or the substances within are exempt by rules for "de minimis concentrations of a toxic chemical in a mixture" §372.38(a).

International Inventories:

US (TSCA): The components within this product are included on the TSCA Inventory of Chemical Substances
Canada (DSL): All ingredients are on the inventory or exempt from listing.
European Union (EINECS): All ingredients conform to the EU requirements.
Japan (ENCS): All other ingredients are on the inventory or exempt from listing.
Philippines (PICCS): All other ingredients are on the inventory or exempt from listing.
South Korea (KECL): All ingredients are on the Inventory or exempt from listing.
Australia (AICS): All ingredients are on the Inventory or exempt from listing.
New Zealand (NZIoC): All ingredients are on the Inventory or exempt from listing.
China (IECSC): All ingredients are on the Inventory or exempt from listing.

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California Proposition 65: There are no chemicals within this mixture on the Proposition 65 List.

Canadian Regulations require the inclusion of the following statements under "Regulatory Information": This product has been classified in accordance with the hazard criteria of the controlled Products Regulations and the SDS contains all the information required by the Controlled Products Regulations.

Section 16: OTHER INFORMATION

Product Codes: H01221, H01222, H01223, H01224, H01225, H01226, H01232, H01304, H01305, H01306, H01469, H01470, H01471, H01472, H01473, H01474, H01475, H01476, H01477, H01478, H01479, H01480, H01481, H01482, H01483, H01484, H01485, H01486, H04035, H04036, H04229, H04230, H04231, H04232, H04233, H04234, H04265, H06753, H07776, H07777, H07778, H07779, H08739, H08740, H08741, H08742, H08743, H08744, H08745, H08746, H08747, H08748, H08749, H08750, H08759, H08760, H08761, H08762, H08763, H08764, H08765, H08766, H08767, H08768, H08769, H08770

NFPA Ratings:

Health: 0
Fire: 0
Reactivity: 0

HMIS Ratings:

Health: 0
Fire: 0
Reactivity: 0

(NFPA and HMIS Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe)

REVISION HISTORY

REVISION	DATE	ECN#	CHG BY	APPR BY	DESC. OF CHANGE
A	09/15/14	14383	TG	SBL	Updated MSDS to GHS/SDS Format. 48205 Revision A supersedes 48068 revision C and48069 revision A.
B	10/15/14	14448	SBL	SBL	Expanded SDS to include all solid-state Gutta Percha Products along with their corresponding product codes in Section 1. Moved product codes to Sec. 16

The information and recommendations set forth herein are presented in good faith and are believed to be correct as of the date hereof. Coltène/Whaledent Inc. however, makes no representations as to the completeness of this information and supplies it on the condition that the persons receiving same will make their own determination as to its suitability of their purposes prior to use. In no event will Coltène/Whaledent Inc. be responsible for damages of any nature whatsoever resulting from use of or reliance upon information.

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