Safety Data Sheet

ANSI Z400.1/Z129.1-2010

Hygenic® SpectraPoint® Guttapercha Points

Section 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name: Hygenic® SpectraPoint® Guttapercha Points

Product Code(s): H08739, H08740, H08741, H08742, H08743, H08744, H08745, H08746, H08747, H08748, H08749, H08750, H07776, H07777

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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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.

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

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.

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

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.

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.