

Hygenic[®] Specialty Resins (Powder Component)

Perm[®] Reline / Repair Resin, Hygenic[®] Repair Resin, Hygenic[®] Orthodontic Resin

Issue Date: September 2014

Internal Document Number: 48294A

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Section 1: PRODUCT AND COMPANY IDENTIFICATION

Product identifier

Product Name: Perm[®] Reline / Repair Resin, Hygenic[®] Repair Resin, Hygenic[®] Orthodontic Resin

Product Code(s): All applicable product codes are listed in Section 16 of this Safety Data Sheet.

Relevant identified uses of the mixture and uses advised against: Intended for dental re-lines, partials, repairs, full dentures, constructing orthodontic appliances and retainers for orthodontic use. Hygenic[®] Specialty Resins are intended for use by a licensed physician.

Synonyms: Acrylic

Manufacturer 
Coltene/Whaledent Inc.
235 Ascot Parkway
Cuyahoga Falls, OH 44223 / USA
Phone: 1 330 916 8800
Fax: 1 330 916 7077
info.us@coltene.com

Authorized EC Representative 
Coltene/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

Classifications: Combustible Dust (Concentration of Benzoyl Peroxide does not justify classification as "Sensitizing")

Appearance: Free-Flowing, White or Pink Powder, Faint Acrylic Odor

Contains: Particulates, Not Otherwise Classified.

Likely Routes of Exposure: Dermal (Skin/Eye), Inhalation, Ingestion

Labeling Elements:

Hazard Category	Signal Word:	Hazard Statements:
Combustible Dust	Warning	May form combustible dust concentrations in air

EUH208 — Contains Benzoyl peroxide. May produce an allergic reaction.

Prevention:	Response:	Storage:	Disposal:
None specified.	None specified.	None specified.	None specified.

Classification in accordance with Directives 67/548/EEC and 1999/45/EC: Not classified as hazardous.

Other hazards which do not result in classification: None.

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 (Synonyms)	CAS	EC Number	Index Number	Percent (w/w)
Polymer	9011-14-7	-	-	60.0-100.0%
Diethyl Phthalate	84-66-2	-	-	0.0-20.00%
Benzoyl Peroxide	94-36-0	202-327-6	617-008-00-0	< 0.1 %

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Section 4: FIRST AID MEASURES

Inhalation: Remove to fresh air. Seek immediate medical attention.

Eyes: If product gets in the eyes, flush with copious amounts of lukewarm water for at least 15 minutes. If irritation occurs, contact a physician.

Ingestion: If ingested, do not induce vomiting. If product has been swallowed, drink plenty of water or milk IMMEDIATELY. If the patient is vomiting, continue to offer water or milk. Never give anything by mouth to an unconscious person. Provide an estimate of the time at which the material was ingested and the amount of the substance that was swallowed. Get medical attention immediately.

Skin: If irritation occurs and product is on the skin, rinse thoroughly with lukewarm water, followed by a thorough washing of the affected area with soap and water. If irritation, redness or swelling persists, contact a physician immediately.

Section 5: FIRE FIGHTING MEASURES

Flammability: Combustible Dust

Flash Point: 304°C (580 °F)

LEL: Not Established

UEL: Not Establish

Extinguishing Media: Water, CO₂, dry chemical or foam.

Specific Hazards Arising from the Chemical: Avoid extinguishing methods that generate a dust cloud.

Protective Equipment and Precautions for Firefighters: Wear NIOSH approved self-contained breathing respirator in positive pressure mode.

Special Hazards: Polymer dust is combustible (at limits similar to coal dust).

Section 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment, and Emergency Procedures: See personal protective equipment listed in section 8.

Methods for Containment and Clean-up: Sweep up dust to avoid slipping hazard.

Other Information: Do not contaminate food or feed with this product. Keep container closed and upright when not in use.

Section 7: HANDLING AND STORAGE

Precautions for Safe Handling: Always wear gloves and eye protection. Wear protective clothing and dust respirator in bulk dust conditions. Keep container closed when not in use.

Conditions for Safe Storage, Including Incompatibilities: Keep out of reach of children. Keep container closed. Store in cool, dry place.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Component Exposure Limits:

Component:	Concentration:	ACGIH TLV - TWA:	OSHA PEL:	NIOSH:	8hr TWA	STEL's	Notation
Polymer	60.0-100.0%	10 mg/m ³	15 mg/m ³	-	-	-	-
Diethyl Phthalate	0.0-20.00%	5 mg/m ³	5 mg/m ³	-	-	-	-
Benzoyl Peroxide	< 0.1%	-	5 mg/m ³	5 mg/m ³	-	-	-

Appropriate Engineering Controls: When working with large quantities of product provide adequate ventilation (e.g., local exhaust ventilation, fans). Ensure that an eyewash station, sink or washbasin is available in case of exposure to eyes. Use good local exhaust at processing equipment, including buffers, sanders, grinders and polishers.

Personal Protective Equipment (Eyes and Face): Depending on the use of this product safety glasses or goggles may be worn. If necessary, refer to U.S. OSHA 29 CFR §1910.133, Canadian standards, or the European Standard EN166. Ensure that an eyewash station, sink or washbasin is available in case of exposure to eyes.

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Personal Protective Equipment (Skin): If anticipated that prolonged & repeated skin contact will occur during use of this product, wear gloves for routine industrial use. If necessary, refer to U.S. OSHA 29 CFR §1910.138, the appropriate standards of Canada, of the E.C. member states.

Personal Protective Equipment (Respiratory): Wear NIOSH/MSHA approved respirator if dust is present. Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Fine, White or Pink Powder.

Odor: Faint Acrylic

Odor Threshold: no data

pH: no data

Melting Point: no data

Specific Gravity: no data

Octanol / H₂O Coefficient (log K_{ow}): no data

Molecular Weight: no data

Auto Ignition: no data

Flash Point: 304 °C (> 212 °F)

Vapor Density: no data

Viscosity: no data

VOC: no data

Boiling Point: no data

Solubility (H₂O): Insoluble in water

Density: no data

Evaporation Rate: no data

Decomposition Temp: no data

LFL: no data

UFL: no data

Vapor Pressure: (25°C) no data

Flammability Class: non-flammable

Section 10: STABILITY AND REACTIVITY

Chemical Stability: Stable under normal dry air conditions

Possibility of Hazardous Reactions: Methacrylate Monomer and Oxides of Carbon when burned.

Conditions to Avoid: Heating above 240 °C, 464 °F.

Incompatibility: Strong Oxidizers

Hazardous Decomposition Products: Methacrylate Monomers and Oxides of Carbon when burned.

Section 11: TOXICOLOGICAL INFORMATION

Likely Routes of Exposure: Dermal (Skin/Eye), Inhalation, Ingestion

This product has NOT been tested on animals to obtain toxicology data. There is toxicology data for the components of the product, which is found in scientific literature. This data has not been presented in this document.

Sensitization: May cause allergy or asthma symptoms or breathing difficulties if inhaled. Human Patch Test:

Approximate one-third of subjects developed mild redness at the site of application. Twenty percent showed sensitivity when tested 10 days later (Benzoyl peroxide).

Carcinogenicity:

IARC: 3 - Group 3: Not classifiable as to its carcinogenicity to humans (Benzoyl peroxide)

NTP & OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen.

Mutagenicity: This product is not reported to produce mutagenic effects in humans.

Reproductive Toxicity: Reproductive toxicity - rat – Intraperitoneal Effects on Fertility: Post-implantation mortality (e.g., dead and/or resorbed implants per total number of implants). Effects on Embryo or Fetus: Fetotoxicity (except death, e.g., stunted fetus). Specific Developmental Abnormalities: Musculoskeletal system. Reproductive toxicity - mouse - male – Oral. Paternal Effects: Spermatogenesis (including genetic material, sperm morphology, motility, and count). Paternal Effects: Prostate, seminal vesicle, Cowper's gland, accessory glands. Effects on Newborn: Live birth index (# fetuses per litter; measured after birth). **Teratogenicity:** Developmental Toxicity - rat – Oral Specific Developmental Abnormalities: Musculoskeletal system. Developmental Toxicity - mouse – Skin Effects on Embryo or Fetus: Fetotoxicity (except death, e.g., stunted fetus). Specific Developmental Abnormalities: Musculoskeletal system

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Specific Target Organ Toxicity - Single Exposure (STOT-SE): No data available**Specific Target Organ Toxicity - Repeated or Prolonged Exposure (STOT-RE):** No data available**Section 12: ECOLOGICAL INFORMATION****Ecotoxicity:** No data available.**Persistence / Degradability:** No data available.**Aquatic Toxicity:** No data available.**Bioaccumulative Potential:** No data available.**Mobility in Soil:** No data available.**Other Adverse Effects:** No data available.**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:** The generation of waste should be avoided or minimized wherever possible. Dispose of unused material in accordance with Federal, State, and Local regulations.**Additional Disposal Considerations:** Dispose if shelf-life has been exceeded.**Section 14: TRANSPORT INFORMATION**

Not hazardous for transportation in quantities provided.

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).**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 of the controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations.**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.**Section 16: OTHER INFORMATION**

National Fire Protection Association (NFPA)

Hazardous Material Information System (HMIS®)

NFPA Ratings:**HMIS Ratings:****Health: 1****Health: 1**

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Fire: 1
Reactivity: 0**Fire: 1**
Reactivity: 0

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

Product Codes: H00325, H00335, H00340, H00345, H00355, H02081, H00327, H00337, H00342, H00347, H00357, H02076, H02082, H00328, H00338, H00343, H00348, H00358, H02077, H02083, H00368, H00377, H00361, H00367, H00370, H00373, H00379, H02079, H02085, H02159, H02160, H02161, H02163, H02165, H02166, H00369, H02080, H00280, H00288, H00292, H00296, H00304, H00289, H00293, H00344, H00354, H00307, H00311, H00313, H00319, H02100, H02099, H02252, H02253, H02101**REVISION HISTORY**

REVISION	DATE	ECN#	CHG BY	APPR BY	DESC. OF CHANGE
A	9/26/14	14407	SBL	SBL	Updated MSDS to GHS/SDS Format. 48294 Revision A supersedes 48051 Revision D.

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.