# **Safety Data Sheet**



ANSI Z400.1/Z129.1-2010

## Hygenic® Acrylic Liquid Cold Cure Monomers

Hyflo<sup>®</sup> Denture Resin, Hygenic<sup>®</sup> Cold Cure Resin, Perm<sup>®</sup> Reline / Repair Resin, Hygenic<sup>®</sup> Orthodontic Resin, Hygon<sup>®</sup> Tray Material

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### Section 1: PRODUCT AND COMPANY IDENTIFICATION

**Product Names: Hygenic<sup>®</sup> Acrylic Liquid Cold Cure Monomers** (Hyflo<sup>®</sup> Denture Resin, Hygenic<sup>®</sup> Cold Cure Resin, Perm<sup>®</sup> Reline / Repair Resin, Hygenic<sup>®</sup> Orthodontic Resin, Hygon<sup>®</sup> Tray Material)

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

**Relevant identified uses of the mixture and uses advised against:** Acrylic Cold Cure Liquid is intended to be mixed with a powder component and used in the construction of dental and orthodontic prosthetics. Federal law restricts this device to sale by or on the order of a physician. Uses advised against: None noted.

Synonyms: None.

### Manufacturer

Coltène/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 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

<u>Classifications:</u> Flammable Liquids (Category 2), Skin Irritation (Category 2), Skin Sensitization (Category 1), Specific Target Organ Toxicity - Single Exposure (STOT-SE Category 3) Respiratory System

Appearance: Clear, Lightly Tinted Liquid With a Sharp, Pungent Odor

Contains: Methyl methacrylate, Ethylene Dimethacrylate

Route(s) of Exposure: Dermal (Eye/Skin), Inhalation, Ingestion

#### **Labeling Elements:**

## Hazard Category

Flammable Liquids (Category 2)
Skin Irritation (Category 2)
Skin Sensitization (Category 1)

Specific Target Organ Toxicity - Single Exposure (STOT-SE Category 3) Respiratory System

#### Prevention:

P210 Keep away from heat/sparks/open flames / hot surfaces. - No smoking. P233 Keep container tightly closed. P240 Ground/bond container and receiving equipment. P241 Use explosion-proof electrical/ ventilating/ lighting / equipment. P242 Use only nonsparking tools. P243 Take precautionary measures against static discharge. P261 Avoid breathing dust/ fume/ gas/ mist/ vapors / spray. P264 Wash skin thoroughly after handling. P271 Use only outdoors or in a well-ventilated area. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

#### Signal Word:

## rd: Hazard Statements:

DANGER H225 Highly flammable liquid and vapor.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction. H335 May cause respiratory irritation.

#### Response:

P303 + P361 + P353 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower. P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P312 Call a POISON CENTER or doctor/ physician if you feel unwell. P321 Specific treatment (see supplemental first aid instructions on this label). P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention. P362 Take off contaminated clothing and wash before reuse. P370 + P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.





#### Storage:

P403 + P233 Store in a wellventilated place. Keep container tightly closed. P403 + P235 Store in a wellventilated place. Keep cool. P405 Store locked up.

### Disposal:

P501
Dispose of contents/ container to an approved waste disposal plant.

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Classification in accordance with Directives 67/548/EEC and 1999/45/EC:. F; R11 Xi; R37/38 R43 (see Section 15 for full text)

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	CAS	EC number	Index Number	Percent (w/w%)
Methyl Methacrylate	80-62-6	201-297-1	607-035-00-6	85 – 95
Ethylene Dimethacrylate	97-90-5	202-617-2	607-114-00-5	2.0 - 5.0

### **Section 4: FIRST AID MEASURES**

**General Advice:** Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous

area.

If Inhaled: If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a

physician.

**Skin Contact:** Wash off with soap and plenty of water. Consult a physician if a reaction occurs.

**Eye Contact:** Flush eyes with water as a precaution.

**If Swallowed:** Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with

water. Consult a physician.

### **Section 5: FIRE FIGHTING MEASURES**

Vapors are flammable at ambient temperatures and atmospheric pressure. Containers may rupture or explode under fire conditions.

**Extinguishing Media:** Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

**Specific Hazards Arising from the Chemical:** Carbon oxides, Flash back possible over considerable distance., Container explosion may occur under fire conditions.

**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. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapors accumulating to form explosive concentrations. Vapors can accumulate in low areas. For personal protection see section 8.

**Methods for Containment and Clean-up:** Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13).

Other Information: See Section 13 for disposal methods.

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### Section 7: HANDLING AND STORAGE

May cause sensitization of susceptible persons by skin contact. For personal protection see section 8. Ground all metal containers during storage and handling.

**Storage Conditions:** Minor deviations (7C/13F) above the recommended temperature (see below) are acceptable for short periods of time (one week) for material in transit. Store in cool place. Keep away from direct sunlight. Material can burn; limit indoor storage to approved areas equipped with automatic sprinklers. Ground all metal containers during storage and handling. This product contains inhibitor to stabilize it during shipment and storage. The effectiveness of the inhibitor is dependent on the presence of dissolved oxygen. In order to maintain sufficient dissolved oxygen in the liquid to avoid polymerization, the monomer must always be stored with a vapor space oxygen concentration of 5% to 21%(air). Store material in containers made of the following: Stainless steel glass Aluminum steel Keep container tightly closed. Storage temperature: <= 38 °C (<= 100 °F) Storage period: 12 Month.

**Other data:** Use monomer within the recommended storage period from date of manufacture to avoid loss of stability or risk of polymerization.

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### **Component Exposure Limits:**

Component:	Concentration:	NIOSH REL:	OSHA PEL:	IDLH:	AIHA WEEL	STEL's	Notation
Methyl Methacrylate	85-95	100 ppm 410 mg/m <sup>3</sup>	100 ppm 410 mg/m <sup>3</sup>	None	None	100 ppm	None
Ethylene Dimethacrylate	2-5	200 ppm	200 ppm	None	None	None	None

Appropriate Engineering Controls: Mechanical vapor capture enclosure and local ventilation should be used.

Personal Protective Equipment (Eyes and Face): wear safety goggles or face shield.

Personal Protective Equipment (Skin): Wear Protective Gloves

Personal Protective Equipment (Respiratory): If exposure is above OSHA PEL, wear a NIOSH approved respirator.

## **Section 9: PHYSICAL AND CHEMICAL PROPERTIES**

Appearance: Clear, Lightly Tinted Liquid Viscosity: 10 cps
Odor: Sharp, Pungent Odor Odor Threshold: No data

pH: No Data Boiling Point:  $101 \, ^{\circ}\text{C} \, (>212 \, ^{\circ}\text{F})$ 

Melting Point: No data Solubility ( $H_2O$ ): 1.6 g/ 100 g water @ 20°C

8.0 lb/gal Specific Gravity: No data Density: Octanol / H<sub>2</sub>O Coefficient: No data **Evaporation Rate:** No data Molecular Weight: No data Decomposition Temp: No data 2.1 % Auto Ignition: No data LFL: Flash Point: 11°C (52°F) UFL: 12.5 %

Vapor Density: No data Vapor Pressure: 29 mmHg @ 20°C

VOC: No data Flammability Class: No data

Explosive Limits in Air: I=1.8%, u=8.2%

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### Section 10: STABILITY AND REACTIVITY

Chemical Stability: Stable in presence of inhibitor.

Materials to Avoid: Reducing and strong oxidizing agents. Material has strong solvent qualities and can soften paint or

rubber.

Hazardous decomposition products: Oxides of Carbon.

Materials to Avoid: Excessive heat, storage without inhibitor, and inadvertent addition of catalyst.

**Reactivity:** Reactive with oxidizing agents and acids.

### Section 11: TOXICOLOGICAL INFORMATION

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

Acute Toxicity: Acute Oral Rat LD50 – 7990 mg/kg, Acute Dermal Rabbit LD50 – 35, 500 mg/kg, Acute Inhalation Rat

12, 500 - 16,  $500 \text{ ppm for } \frac{1}{2} \text{ hour}$ 

**Primary Effects to Skin:** Allergic reaction can occur by repeated direct contact.

Primary Effects to Eyes: Irritation can occur by repeated direct contact.

Primary Effects to Respiratory System: Overexposure to vapors may cause respiratory tract irritation and

central nervous system depression.

**Ingestion:** No data available.

Sensitization: Human allergic responses have been observed.

Carcinogenicity: Methyl Methacrylate is listed by IARC as Group 3 "not classifiable as human carcinogens". Product

does not contain carcinogens listed with NTP or ACGIH.

**Teratogenicity:** MMA did not cause birth defects, malformations, or fetal toxicity in pregnant rats inhaling

concentrations up to 2028 ppm.

**Additional Toxicological Info:** In a retrospective study of the effects of exposure to ethyl acrylate and methyl methacrylate on workers hired in one plant between 1933 and 1945, a higher-than-expected incidence of colorectal cancer mortality was observed. However, there was no association of risk in similarly exposed populations from other locations or in subsequent evaluations of the same location.

The National Toxicology Program used rats with chronic inhalation at concentration up to 1000 ppm which caused nasal irritation, inflammation of the nasal cavity and degeneration of the olfactory epithelium.

## **Section 12: ECOLOGICAL INFORMATION**

### **Ecotoxicity:**

Toxicity to Fish	LC50 - Pimephales promelas (fathead minnow) - 125.5 - 275.0 mg/l - 96 h
Toxicity to Daphnia and Other Aquatic Invertebrates	EC50 - Daphnia magna (Water flea) - 720 mg/l
Toxicity to Algae	EC50 - Pseudokirchneriella subcapitata (green algae) - 170 mg/l - 96 h

Persistence / Degradability: No data available.

Bioaccumulative Potential: The product has low potential for bioaccumulation.

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).

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### Section 13: DISPOSAL CONSIDERATIONS

**Disposal:** CAUTION - Keep spills and cleaning runoff out of municipal sewers and open bodies of water. Do not allow material to contaminate ground water system.

May be disposed of as household waste after polymerization, if the necessary technical regulations are observed and after consulting the disposer and the responsible authority.

EWC: European Waste catalogue(EWC) 07 02 99: Waste not otherwise specified.

**RCRA:** Characteristic Waste D001 - When a decision is made to discard this material as supplied, it is classified as a RCRA hazardous waste with the characteristic of ignitability. After the addition of excess inhibitor, incinerate liquid and contaminated diking material in accordance with local, state, and federal regulations.

**Contaminated packaging:** Dispose of as unused product. CONTAINERS MAY BE HAZARDOUS WHEN EMPTY. Since emptied containers retain product residue follow all SDS and label warnings even after container is emptied. Do not burn, or use a cutting torch on, the empty drum. Improper disposal or re-use of this container may be dangerous and illegal. Refer to applicable local, state and federal regulations.

Additional Disposal Considerations: Dispose if shelf-life has been exceeded.

### Section 14: TRANSPORT INFORMATION

### **Emergency Response Guide Number: 129**

Agency	Proper Shipping name	UN-No.	Hazard Class	Label
DOT	Methyl methacrylate monomer, stabilized	UN1247	3 PG II RQ 1000 lbs	
Sea Transport IMDG/GGV Sea	Methyl methacrylate monomer, stabilized	UN1247	3 PG II EmS F-E S-D	FLAMMABLE
Air Transport ICAO-Ti and IATA-DGR	Methyl methacrylate monomer, stabilized	UN1247	3 PG II	3

### For shipments where the containers do not exceed 5L (5 Liter = 1.3 Gallons):

Agency	Proper Shipping name	UN-No.	Hazard Class	Label
DOT / International Ground	Consumer Commodity	ID8000	Consumer Commodity	ORM-D
Sea Transport IMDG/GGV Sea	Methyl methacrylate	ID8000	Consumer Commodity	A V
Air Transport ICAO-Ti and IATA-DGR	monomer, stabilized	ID8000	Consumer Commodity	FLAMMABLE Y and

### **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.

SARA Sections 311 and 312: Acute Health Hazard, Chronic Health Hazard, Fire Hazard, Reactivity Hazard.

**CERCLA:** This material is regulated under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and the Superfund Amendments and Reauthorization Act (SARA) Title III Section 304. This material is or contains chemical(s) listed in 40 CFR Table 302.4 or nondesignated RCRA ICR substance(s). (Nondesignated ICR substances apply to materials that will not be reused.) The Reportable Quantity(s) (RQ) are listed below. Releases in

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excess of its reportable quantity must be reported to the National Response Center (1-800-424-8802) and to the appropriate state and local emergency response organizations.

SARA Section 313: Substance	CAS	Percent (w/w%)
Methyl Methacrylate	80-62-6	85-95
Ethylene Glycol Dimethacrylate	97-90-5	2-5

#### 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:** This Product Contains Chemicals Known To The State of California To Cause Cancer: N,N-Dimethyl-p-toluidine / CAS# 99-97-8 (< 1%w/w).

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.

Classification in accordance with Directives 67/548/EEC and 1999/45/EC (full text): F – Flammable, R11 - Highly flammable, Xi – Irritant, R37/38 - Irritating to respiratory system and skin, R43 - May cause sensitization by skin contact

## **Section 16: OTHER INFORMATION**

NFPA Ratings: HMIS Ratings:

Health: 2
Fire: 3
Fire: 3
Reactivity: 2
Health: 2
Fire: 3
Reactivity: 2

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

**Product Codes:** H00248, H00257, H00260, H00266, H00276, H00277, H02033, H00325, H00335, H00340, H00345, H00355, H02081, H00327, H00337, H00342, H00347, H00357, H02076, H02082, H00328, H00338, H00343, H00348, H00358, H02077, H02083, H00368, H00377, H00382, H00383, H00384, H02253, H02102, H03343, H00280, H00292, H00296, H00304, H00289, H00293, H00344, H00354, H00321, H00322, H00323, H02100, H02252, H02103, H03342, H02099, H00388, H00389, H00390, H00391, H00392, H00393, H00394, H00395, H00396, H00415, H00416, H00417, H01016, H01020, H01021, H01045, H01046, H02032, 50007656, 3-ALB301, 50007653, 3-ALB201, 50007654, 3-ALB202, 50007658, 3-ALB601, 50007652, 3-ALB101

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# Hygenic® Acrylic Liquid Cold Cure Monomers

Hyflo® Denture Resin, Hygenic® Cold Cure Resin, Perm® Reline / Repair Resin, Hygenic® Orthodontic Resin, Hygon® Tray Material

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	REVISION HISTORY									
REVISION	DATE	ECN#	CHG BY	APPR BY	DESC. OF CHANGE					
А	09/30/2014	14410	TG	SBL	Updated MSDS to GHS/SDS Format. 48290 Revision A supersedes 48135 revision A.					
В	10/09/2014	14435	SBL	SBL	Added Hygon Tray Material in Section 1 and title. Also added corresponding Product Codes. Added Limited quantity ground symbol to Section 14.					

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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# Hygenic<sup>®</sup> Specialty Resins (Powder Component)

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

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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<sup>®</sup> Specialty Resins are intended for use by a licensed physician.

Synonyms: Acrylic

Manufacturer Authorized EC Representative Emergency Contact Number:

Coltène/Whaledent Inc. Coltène/Whaledent GmbH + Co. KG USA & Canada: 1 800 535 5053

235 Ascot Parkway Raiffeisenstraße 30 Cuyahoga Falls, OH 44223 / USA 89129 Langenau

Phone: 1 330 916 8800 Phone: 49 7345 805 0
Fax: 1 330 916 7077 Fax: 49 7345 805 201
info.us@coltene.com info.de@coltene.com

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.

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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# Hygenic<sup>®</sup> Specialty Resins (Powder Component)

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

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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

LEL: Not Established Flash Point: 304°C (580 °F) **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

### 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 <sup>3</sup>	15 mg/m <sup>3</sup>	-	-	-	-
Diethyl Phthalate	0.0-20.00%	5 mg/m <sup>3</sup>	5 mg/m <sup>3</sup>	-	-	-	-
Benzoyl Peroxide	< 0.1%	-	5 mg/m <sup>3</sup>	5 mg/m <sup>3</sup>	-	-	-

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

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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. Viscosity: no data

Odor: Faint Acrylic VOC: no data

Odor Threshold: no data

Boiling Point: no data

pH: no data Solubility (H₂O): Insoluble in water

Melting Point: no data

Density: no data

Specific Gravity: no data

Evaporation Rate: no data

Octanol / H<sub>2</sub>O Coefficient (log K<sub>ow</sub>): no data

Decomposition Temp: no data

Molecular Weight: no data

LFL: no data

Auto Ignition: no data

UFL: no data

Flash Point: 304 °C (> 212 °F)

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 vessicle, 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

# **Safety Data Sheet**



ANSI Z400.1/Z129.1-2010

# Hygenic® Specialty Resins (Powder Component)

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

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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

# **Safety Data Sheet**



ANSI Z400.1/Z129.1-2010

# Hygenic<sup>®</sup> Specialty Resins (Powder Component)

Perm<sup>®</sup> Reline / Repair Resin, Hygenic<sup>®</sup> Repair Resin, Hygenic<sup>®</sup> Orthodontic Resin

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Fire: 1 Fire: 1
Reactivity: 0 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.

P/N 90623-294 REVISION: A ECO: 13312