SAFETY DATA SHEETS

This SDS packet was issued with item:

073794898

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

073783743 073800018 073800042 073800109 073800133 073800166 073800224 073800240 073800265 073801909 073805272

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).

073782687 073782711 073782802 073782836 073782869 073782893 073782927 073782950 073783156 073783172 073783230 073783255 073783263 073783271 073783537 073783594 073783651 073783719 073784402 073786241 073786282 073794880 073797974 073798006 073798063 073798097 073798121 073798147 073798618 073798642 073798709 073798733 073798766 073798790 073798824 073798832 073798840 073798857 073798865 073798899 073798907 073798915 073798923 073798931 073798949 073798956 073798964 073802394 073803376 073803434

Date of Issue: May 2013 Supersedes version of: November 2010 Page 1 of 2 n.a = not applicable, n.k. = not known P/N 48135A

Identification of the substance / preparation and of the company / undertakings Product Details:

Trade Name: Hygenic® Acrylic Liquid - Cold Cure Monomers

(Hyflo®, Cold Cure, Perm® Reline/Repair, Hygenic® Repair, Orthodontic, Hygon® Tray)

Manufacturer:

Coltène/Whaledent Inc.

235 Ascot Parkway Cuyahoga Falls, OH 44223 / USA Fax +1 330 916 7077

info@coltenewhaledent.com

Emergency Contact Numbers: USA & Canada: 1 800 535 5053 Main Phone Number: +1 330 916 8800 Authorized EU Representative Coltène/Whaledent GmbH+ Co. KG

Raiffeisenstrasse 30 89129 Langenau / Germany Tel. +49 (0) 7345 805 0 Fax +49 (0) 7345 805 201

2. Hazard Identification

Hazard Designation: Flammable Liquid

Information pertaining to particular dangers for man and environment: Flammable Liquid, skin sensitizer, respiratory irritant Classification is in line with BC directive 1999/45/EEC: Not Applicable (N/A)

3. Composition / Information on Ingredients

Chemical Characterization: Methyl Methacrylate Monomer, Inhibited

Hazardous ComponentsWt %Index, R/S PhrasesMethyl Methacrylate, Inhibited> 1%F, R-11,37,38,43N,N-Dimethyl-p-toluidine< 1%</td>n.kEthylene Glycol DiMethacrylate> 1%n.k

4. First-Aid Measures

After Inhalation: Get to fresh air, if not breathing, administer artificial respiration. If discomfort persists, seek medical attention.

After Skin Contact: Wash thoroughly with water for 15 minutes. If irritation persists, consult a physician

After Eye Contact: Flush with water for 15 minutes. If irritation persists, consult a physician After Swallowing: In the event of ingestion, call a physician immediately. Do not induce vomiting.

5. Fire-Fighting Measures

Flammability: Flammable Flash Point: 11°C (52°F) LEL: 1.8% UEL: 8.2%

Extinguishing Media: Use alcohol foam, carbon dioxide or dry chemical to extinguish fire.

Unsuitable Extinguishing Media: Water stream may be ineffective.

Protective Equipment: Wear NIOSH approved self-contained breathing respirator in positive pressure mode and full firefighting protective clothing.

Special Hazards: Heat and pressure in closed containers may result in polymerization. Vapor is heavier than air and may travel a considerable distance to source of ignition and flash back.

6. Accidental Release Measures

Personal Precautions: Remove any sources of ignition, sparks and flame. Avoid contact with eyes. Wear self-contained positive pressure breathing apparatus and full firefighting protective clothing.

Environmental Precautions: Cover spills with an inert absorbent material; soak up and place in an appropriate disposal container. For large spills, a professional HAZMAT Team should handle it.

7. Handling and Storage

Precautions for Safe Handling: Avoid contact with eyes and skin. Always wear gloves and eye protection. Use with adequate ventilation. Keep container closed when not in use.

Storage: Store in cool dry container. Keep out of direct sunlight. Storage areas should comply with all appropriate Federal, State and Local regulations. Keep out of reach of children. Keep container closed.

Further Information on Storage: Open container periodically to see if product has polymerized. Do not use after expiration date.

8. Exposure Controls/Personal Protection

Components with recommended limits for the work place

CAS No. Description Wt% Type / Value Methyl Methacrylate, Inhibited 80-62-6 > 1% OSHA PEL 100 ppm N,N-Dimethyl-p-toluidine Not Established 99-97-8 < 1% OSHA PEL Ethylene Glycol DiMethacrylate OSHA PEL 97-90-5 > 1% Not Established

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

Work/Hygienic Protection: Wash hands and equipment after use.

Hand/Skin Protection: Wear Protective Gloves

Respiratory Protection: If exposure is above OSHA PEL, wear a NIOSH approved respirator.

Eye Protection: Wear Safety Goggles

Material Safety Data Sheet in Accordance with 2001/58/EEC & ANSI Z400.1/Z129.1-2010

Date of Issue: May 2013 Coltène/Whaledent Inc. Page 2 of 2 Hygenic® Acrylic Liquid - Cold Cure Monomers n.a = not applicable, n.k. = not known P/N 48135A **Physical And Chemical Properties** Solubility: 1.6 g/ 100 g water @ 20°C Method: Tag Closed Cup Appearance: Clear, lightly tinted liquid Odor: sharp, pungent Boiling Point: 101 °C (>212 °F) Flash Point: 11 °C (52 °F) Flammability: Yes Auto flammability: n.k. Density: 8.0 lb/gal Vapor Pressure: 29 mmHg @ 20°C Explosive Properties: n.e. Explosive Limits in Air: I=1.8%, u=8.2% Viscosity: 10 cps Method: n.a. pH: n.a.

10. Stability and Reactivity

Chemical Stability: Stable in presence of inhibitor

Conditions to avoid: Excessive heat, storage without inhibitor,

and inadvertent addition of catalyst.

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

11. Toxicological Information

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

Acute Inhalation Rat 12,500 – 16,500 ppm for ½ 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

Sensitization: N.A

Additional Toxicological Info: The national Toxicology program used rats with chronic inhalation @ concentration up to 1000 ppm which caused nasal irritation, inflammation of the nasal cavity and degeneration of the olfactory epithelium.

12. Ecological Information

General Information: Liquid with moderate volatility. Product is sparingly soluble in water. The product has low potential for Bioaccumulation. Low Toxicity to fish.

Classification of Water endangerment: N.A.

13. Disposal Considerations

Product: This material is to be treated as a special waste material. Follow Federal, State and Local regulatory laws for proper disposal. If determined to be a hazardous waste as classified by RCRA, then incinerate in an EPA approved facility. Completely polymerized materials can be disposed of together with household refuse in accordance with local regulatory laws.

14. Transportation Information

DOT Shipping Name: DOT Hazard Class: UN-No.

Methyl Methacrylate Monomer, stabilized 3 UN 1247, Packing Group II

Sea Transport IMDG/GGV Sea

Class: 3.2 UN. No.: 1247, Packing Group II. EmS-No: N.A. MFGA-No: N.A.

Air Transport ICAO-Ti and IATA-DGR

Class: 3 UN. No.: 1247, Packing Group II

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: Flammable Liquid SARA 302 Extremely Hazardous Substances: None

SARA 313 Toxic Chemicals

 Chemical Name
 CAS-No.
 Weight %

 Methyl Methacrylate, Inhibited
 80-62-6
 > 1%

 N,N-Dimethyl-p-toluidine
 99-97-8
 < 1%</td>

 Ethylene Glycol DiMethacrylate
 97-90-5
 > 1%

Classification According to EEC Guidelines:

Index: F, Xi R-Phrases – R11, 37, 38, 43 S-Phrases – S 24, 37, 46

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: Changed to Company Format and Updated Address 12/06/03. Added Aurthorized EU Rep. 5/5/04. 1/11/06 Biannual review. Changed Header to acknowledge 2001/58/EEC in place of 91/155/EEC. Changed Sect 3 to call out 1999/45/EEC. 11/29/10 Review, no changes. 5/21/13 Part Number 48135A was 3-P01817C, switched sections 2 & 3, ANSI Z400.1/Z129.1-2010 was ANSI 400.1-2003.

Definitions

F - Highly Flammable, Xi - Irritant

R11 - Highly Flammable, R37/38 - Irritation to respiratory system and skin, R43 - May cause sensitization by skin contact

S2- Keep out of reach of children, S24 - Avoid contact with skin, S37 - Wear Suitable Gloves

S46 - If swallowed, seek medical advice immediately and show this container of label.

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.

Safety Data Sheet



ANSI Z400.1/Z129.1-2010

Hygenic[®] Specialty Resins (Powder Component)

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

Issue Date: September 2014 Internal Document Number: 48294A Page 1 of 5

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 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. 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 %

Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

Safety Data Sheet



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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.

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

Boiling Point: no data

Solubility (H₂O): Insoluble in water

Density: no data

VOC: 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 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

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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 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	
А	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.