

Hygenic[®] Acrylic Liquid Cold Cure Monomers

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

Revision Date: October 2014

Internal Document Number: 48290B

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Section 1: PRODUCT AND COMPANY IDENTIFICATION

Product Names: Hygenic[®] Acrylic Liquid Cold Cure Monomers (Hyflo[®] Denture Resin, Hygenic[®] Cold Cure Resin, Perm[®] Reline / Repair Resin, Hygenic[®] Orthodontic Resin, Hygon[®] 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

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

Section 2: HAZARDS IDENTIFICATION

Classifications: 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

Signal Word:

DANGER

Hazard Statements:

H225 Highly flammable liquid and vapor.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.



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 non-sparking 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.

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 well-ventilated place. Keep container tightly closed. P403 + P235 Store in a well-ventilated 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 ³	100 ppm 410 mg/m ³	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 °C (>212 °F)
Melting Point:	No data	Solubility (H ₂ O):	1.6 g/ 100 g water @ 20°C
Specific Gravity:	No data	Density:	8.0 lb/gal
Octanol / H ₂ O Coefficient:	No data	Evaporation Rate:	No data
Molecular Weight:	No data	Decomposition Temp:	No data
Auto Ignition:	No data	LFL:	2.1 %
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:	l=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 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.

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	
Air Transport ICAO-Ti and IATA-DGR	Methyl methacrylate monomer, stabilized	UN1247	3 PG II	

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	 
Sea Transport IMDG/GGV Sea	Methyl methacrylate monomer, stabilized	ID8000	Consumer Commodity	 
Air Transport ICAO-Ti and IATA-DGR		ID8000	Consumer Commodity	

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:

Health: 2
Fire: 3
Reactivity: 2

HMIS Ratings:

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, H00288, 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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REVISION HISTORY

REVISION	DATE	ECN#	CHG BY	APPR BY	DESC. OF CHANGE
A	09/30/2014	14410	TG	SBL	Updated MSDS to GHS/SDS Format. 48290 Revision A supersedes 48135 revision A.
B	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.