

**1. Product and company identification**

**Product identifier**

Trade name: 617H19 - ORTHOCRYL Lamination Resin

**Relevant identified uses of the substance or mixture and uses advised against**

General use: Lamination Resin for orthopedic procedures  
Reserved for industrial and professional use.

**Details of the supplier of the safety data sheet**

Company name: Otto Bock Health Care  
Street/POB-No.: 3820 W. Great Lakes Drive  
Postal Code, city: Salt Lake City, UT 84120  
USA

WWW: www.ottobockus.com

Telephone: +1 (801) 956-2400

Telefax: +1 (801) 956-2401

Dept. responsible for information:

Quality Department,  
Telephone: +1 (801) 954-2304 (7 AM – 3 PM, Mountain Time),  
Email: USRegulatory@ottobock.com

Additional information: Corporate headquarters:  
Ottobock SE & Co. KGaA  
Max-Näder-Straße 15  
Duderstadt  
Germany

**Emergency phone number**

**CHEMTREC, Telephone: +1 (800) 424-9300**

**Transport:**

**CONSULTANK Lutz Harder GmbH (Contract QUALI003)**

**Telephone: +49 (0)178-4337434 (from USA: 01149 178 4337434)**

**2. Hazards identification**

**Emergency overview**

Appearance: Form: liquid  
Color: colorless

Odor: ester-like

Classification: Flammable Liquid - Category 2; Skin Irritation - Category 2; Sensitization - skin - Category 1; Specific Target Organ Toxicity (Single Exposure) - Category 3;

Hazard symbols:



Signal word: **Danger**

Hazard statements: Highly flammable liquid and vapor.  
 Causes skin irritation.  
 May cause an allergic skin reaction.  
 May cause respiratory irritation.

Precautionary statements: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
 Do not get in eyes, on skin, or on clothing.  
 Use only outdoors or in a well-ventilated area.  
 Wear protective gloves/protective clothing/eye protection/face protection.  
 If skin irritation or rash occurs: Get medical advice/attention.  
 Store in a well-ventilated place. Keep cool.

**Regulatory status**

This material is considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200) and SIMDUT in Canada.

**Hazards not otherwise classified**

Watch for exothermic reactions with peroxides. Due to reducing substances and heavy metal ions polymerization with heat generation may occur.  
 Concentrated vapors are heavier than air. Electrostatic charge.  
 Methyl methacrylate: Explosive mixtures with air may even form at room temperature.  
 Can damage your health.  
 see section 11: Toxicological information

**3. Composition / Information on ingredients**

Chemical characterization: Solution of acrylic polymers in methylmethacrylate, containing softener. (MMA)

Relevant ingredients:

CAS No.	Designation	Content	Classification
CAS 80-62-6	Methyl methacrylate	40 - 70 %	Flammable Liquid - Category 2. Skin Irritation - Category 2. Sensitization - skin - Category 1. Specific Target Organ Toxicity (Single Exposure) - Category 3.
CAS 38668-48-3	1,1'-(p-Tolylimino) dipropan-2-ol	0.1 - 1 %	Acute Toxicity - oral - Category 2. Eye Irritation - Category 2A. Aquatic toxicity - acute - Category 3. Aquatic toxicity - chronic - Category 3.

**4. First aid measures**

General information: Take off immediately all contaminated clothing.  
 In case of accident or if you feel unwell, seek medical advice immediately.

In case of inhalation: Move victim to fresh air, put at rest and loosen restrictive clothing. If breathing becomes irregular or ceases, apply rescue breathing or artificial respiration immediately, where required supply oxygen. Seek medical attention.

Following skin contact: After contact with skin, wash immediately with soap and plenty of water.  
 Seek medical attention if irritation persists.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Subsequently consult an ophthalmologist.

After swallowing: Do not induce vomiting. Immediately get medical attention.

**Most important symptoms/effects, acute and delayed**

Irritant. May cause an allergic skin reaction.  
In case of inhalation Mucous membrane irritation, Cough and shortage of breath. In case of prolonged exposure: headache, drowsiness

**Information to physician**

Monitor breathing.  
Treat symptomatically.

## 5. Fire fighting measures

Flash point/flash point range:

50 °F (DIN 51755 (MMA))

Auto-ignition temperature: No data available

Suitable extinguishing media:

Foam, dry chemical powder, carbon dioxide

Extinguishing media which must not be used for safety reasons:

Water

**Specific hazards arising from the chemical**

Highly flammable liquid and vapor. Concentrated vapors are heavier than air.  
Methyl methacrylate: Explosive mixtures with air may even form at room temperature.  
In case of fire may be liberated: Sulphur oxides, carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters:

Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information: Cool endangered containers with water spray and, if possible, remove from danger zone.  
Do not allow fire water to penetrate into surface or ground water.

## 6. Accidental release measures

Personal precautions: Keep away from sources of ignition - No smoking. Provide adequate ventilation.  
Wear appropriate protective equipment. Avoid contact with skin and eyes.  
Avoid breathing vapors. When vapors form, use respiratory protection.

Environmental precautions:

Do not allow to enter into ground-water, surface water or drains.

Methods for clean-up:

Smaller amounts: Soak up with absorbent materials such as sand, siliceus earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance.  
In case of greater quantities: Collect mechanically (use only explosion-proof equipment when pumping out).

Additional information:

Use explosion-proof equipment and non-sparking tools/utensils.

## 7. Handling and storage

**Handling**

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed.  
Provide room air exhaust at ground level. Concentrated vapors are heavier than air.  
Wear appropriate protective equipment. Avoid contact with skin and eyes.  
Avoid breathing vapors. When vapors form, use respiratory protection.

Precautions against fire and explosion:

Keep away from sources of ignition - No smoking.  
 Take precautionary measures against static discharges.  
 Concentrated vapors are heavier than air. Flammable mixtures may form in the air when product is heated above the flash point and/or during spraying.  
 Use only explosion-proof equipment.

**Storage**

Requirements for storerooms and containers:

Keep only in the original container at temperature not exceeding 95 °F.  
 Keep container tightly closed. Protect from light.  
 Because oxygen (air) is necessary to stabilize product, fill container only to 90% of capacity.  
 Provide adequate oxygen (air) circulation for large containers to ensure product stability.

Hints on joint storage:

Do not store together with organic peroxides, ammonia or persulphates.

**8. Exposure controls / personal protection**

**Exposure guidelines**

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
80-62-6	Methyl methacrylate	USA: ACGIH: STEL	410 mg/m <sup>3</sup> ; 100 ppm
		USA: ACGIH: TWA	205 mg/m <sup>3</sup> ; 50 ppm
		USA: NIOSH: TWA	410 mg/m <sup>3</sup> ; 100 ppm
		USA: OSHA: TWA	410 mg/m <sup>3</sup> ; 100 ppm

Additional information:

National regulations Germany - Methyl methacrylate:  
 Limitation of exposure peaks - category I (Local irritants): Peak level 2 x OEL - Maximum duration per shift: 5 min., momentary value - Maximum frequency per shift: 8.  
 Pregnancy risk group C:  
 There is no reason to fear a risk of damage to the embryo or foetus when TLV values are observed.

**Engineering controls**

Provide for good ventilation or exhaust system or work with completely self-contained equipment.  
 See also information in chapter 7, section storage.

**Personal protection equipment (PPE)**

- Eye/face protection: Tightly sealed goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010.
- Skin protection: When handling larger quantities: face protection, rubber boots and rubber apron.  
 Protective gloves according to OSHA Standard - 29 CFR: 1910.138.  
 Glove material: butyl caoutchouc (butyl rubber)-Layer thickness 0,7 mm.  
 Observe glove manufacturer's instructions concerning penetrability and breakthrough time.
- Respiratory protection: Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded.  
 Use filter type A (= against vapors of organic substances) according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.

General hygiene considerations:

- Avoid breathing vapors.
- Avoid contact with skin and eyes.
- Wash hands before breaks and after work.
- Separate storage of work clothes.
- Take off immediately all contaminated clothing.
- Keep away from sources of ignition - No smoking.

**9. Physical and chemical properties**

**Information on basic physical and chemical properties**

Appearance:	Form: liquid Color: colorless
Odor:	ester-like
Odor threshold:	No data available
pH value:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	212.9 °F (1013 hPa (MMA))
Flash point/flash point range:	50 °F (DIN 51755 (MMA))
Evaporation rate:	No data available
Flammability:	Highly flammable liquid and vapor.
Explosion limits:	LEL (Lower Explosion Limit): 2.10 Vol-% (Methyl methacrylate) UEL (Upper Explosive Limit): 12.50 Vol-% (Methyl methacrylate)
Vapor pressure:	at 68 °F: (MMA) 47 hPa
Vapor density:	No data available
Density:	at 68 °F: approx. 1 g/mL
Water solubility:	at 68 °F: (MMA) 16 g/L
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	No data available
Viscosity, dynamic:	at 68 °F: approx. 500 mPa*s
Explosive properties:	Methyl methacrylate: Explosive mixtures with air may even form at room temperature.
Ignition temperature:	806 °F (DIN 51794 (MMA))
Additional information:	Relative vapor density at 68 °F (air=1): >1

**10. Stability and reactivity**

Reactivity:	Highly flammable liquid and vapor. Concentrated vapors are heavier than air. Methyl methacrylate: Explosive mixtures with air may even form at room temperature.
Chemical stability:	Product is stable under normal storage conditions.

Possibility of hazardous reactions

Product is normally delivered in a stable state. However, if shelf life and/or recommended storage temperature are exceeded to a large degree, product may polymerize and generate heat.

Due to reducing substances, peroxides and heavy metal ions, polymerization with heat generation may occur.

Conditions to avoid: Keep away from heat sources, sparks and open flames.  
Protect from light.

Incompatible materials: Amines, sulphur compounds, alkali compounds, reducing agent, oxidizing agents.  
Watch for exothermic reactions with peroxides. Due to reducing substances and heavy metal ions polymerization with heat generation may occur.

Hazardous decomposition products:  
In case of fire may be liberated: Sulphur oxides, carbon monoxide and carbon dioxide.

Thermal decomposition: No data available

## 11. Toxicological information

### Toxicological tests

Acute toxicity: LD50 Rat, oral: (MMA) > 5000 mg/kg  
LD50 Rabbit, dermal: (MMA) > 5000 mg/kg  
LC50 Rat, inhalative: (MMA) 29.8 mg/L/4h  
NOAEL Rat, inhalative: (MMA) 25 ppm/2a  
NOAEL Rat, oral: (MMA) 2000 ppm/2a

Toxicological effects: Acute toxicity (oral): Lack of data.  
Acute toxicity (dermal): Lack of data.  
Acute toxicity (inhalative): Lack of data.  
Skin corrosion/irritation: Skin Irritation - Category 2 = Causes skin irritation.  
Serious eye damage/irritation: Lack of data.  
Sensitisation to the respiratory tract: Lack of data.  
Skin sensitisation: Sensitization - skin - Category 1 = May cause an allergic skin reaction.  
Germ cell mutagenicity/Genotoxicity: Lack of data.  
Carcinogenicity: Lack of data.  
Reproductive toxicity: Lack of data.  
Effects on or via lactation: Lack of data.  
Specific target organ toxicity (single exposure): Specific Target Organ Toxicity (Single Exposure) - Category 3 = May cause respiratory irritation.  
Specific target organ toxicity (repeated exposure): Lack of data.  
Aspiration hazard: Lack of data.

Other information: Following information applies to the component Methyl methacrylate:  
 High concentrations of vapor or inhalation for an extended period may lead to paralysis of the central nervous system. Pulmonary edema is possible.  
 Sensitization:  
 Varying incidences of allergic reactions have been observed in humans. Symptoms: Headache, eye irritations, skin problems.  
 Mutagenicity:  
 Ames test (Salmonella typhimurium, Dose 10000 µg/plate): not a mutagen  
 Mouse, Lymphoma L 5178 Y TK+/-Cells: mutagenic  
 CHO-Cells: Slight increase of the SCE (SCE-test).  
 No increase of the number of micronucleides under the following test conditions:  
 OECD 474: 4520 mg/kg/Dose 1 - 1130 mg/kg/Dose 4.  
 CD-1 Mouse, male, 6h/d, 5d: not a mutagen (Dominant letal Test).  
 Teratogenicity:  
 Rat, inhalative: 2028 ppm, 6 - 15 d.  
 Product did not show any carcinogenous, mutagenous or teratogenic effects in animal experiments.  
 Chronic toxicity:  
 Rat, inhalative 250 - 1000 ppm (6h/d, 5d/w) exceeding 2a).  
 Symptoms: Damage of the mucous membranes in nose, throat and lungs. Degeneration of olfactory epithelia.  
 Mouse, inhalative 500 - 1000 ppm (6h/d, 5d/w) exceeding 2a).  
 Symptoms: Damage of the mucous membranes in nose, throat and lungs. Degeneration of olfactory epithelia.  
 Following information applies to the component N,N-Bis-(2-hydroxypropyl)-p-toluidine:  
 LD50 Rat, oral: 172 mg/kg

**Symptoms**

In case of prolonged exposure: headache, drowsiness  
 In case of inhalation: Mucous membrane irritation, Cough and shortage of breath.  
 In case of ingestion: Methyl methacrylate:  
 Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.  
 Can damage your health.  
 After eye contact: May cause irritations.

**12. Ecological information**

**Ecotoxicity**

Aquatic toxicity: Following information applies to the component Methyl methacrylate:  
 Algae toxicity:  
 EC3 Scenedesmus quadricauda: 37mg/L/8d (DIN 38412 T.9)  
 Bacterial toxicity:  
 EC0 Pseudomonas putida: 100 mg/L  
 Daphnia toxicity:  
 EC50 Daphnia magna (Big water flea): 69mg/L/48h (OECD 202)  
 EC50 Daphnia magna (Big water flea): 49 mg/L/21d (OECD 202/2)  
 LOEL Daphnia magna (Big water flea): 68mg/L/21d (OECD 202/2)  
 NOEL Daphnia magna (Big water flea): 37mg/L/21d (OECD 202/2)  
 Fish toxicity:  
 LC50 Oncorhynchus mykiss >79 mg/L/96h (OECD 203)

**Mobility in soil**

No data available

**Persistence and degradability**

Further details: Biodegradation: 94 %/14 d (MMA, OECD 301C.)  
 Product is readily biodegradable.  
 Ethylene di(S-thioacetate): not readily biodegradable (according to OECD criteria).

**Additional ecological information**

Volatile organic compounds (VOC): approx. 50 % by weight = 500 g/L  
 General information: Do not allow to enter into ground-water, surface water or drains.  
 In case of spills of large quantities: Danger to drinking water.

**13. Disposal considerations**

**Product**

Recommendation: Incinerate as hazardous waste according to applicable local, state, and federal regulations.

**Contaminated packaging**

Recommendation: Dispose of waste according to applicable legislation.  
 Handle contaminated packages in the same way as the substance itself.  
 Non-contaminated packages may be recycled.

**14. Transport information**

**USA: Department of Transportation (DOT)**

Identification number: UN1866  
 Proper shipping name: UN 1866, UN 1866, resin solution  
 Hazard class or Division: 3  
 Packing Group: III  
 Labels: 3  
 Special provisions: B1, B52, IB3, T2, TP1  
 Packaging – Exceptions: 150  
 Packaging – Non-bulk: 173  
 Packaging – Bulk: 242  
 Quantity limitations – Passenger aircraft / rail: 60 L  
 Quantity limitations – Cargo only: 220 L  
 Vessel stowage – Location: A





**617H19 - ORTHOCRYL Lamination Resin**

Material number 617H19

Page: 9 of 11

**Sea transport (IMDG)**

UN number: UN 1866  
Proper shipping name: UN 1866, Resin solution  
Class or division, Subsidiary risk: Class 3, Subrisk -  
Packing Group: III  
EmS: F-E, S-E  
Special provisions: 223, 955  
Limited quantities: 5 L  
Excepted quantities: E1  
Contaminated packaging - Instructions: P001, LP01  
Contaminated packaging - Provisions: PP1  
IBC - Instructions: IBC03  
IBC - Provisions: -  
Tank instructions - IMO: -  
Tank instructions - UN: T2  
Tank instructions - Provisions: TP1  
Stowage and handling: Category A.  
Properties and observations: Miscibility with water depends upon the composition.  
Marine pollutant: no  
Segregation group: none  
Remarks: Attention! IMDG 2.3.2.3: single pack >= 30 L --> PG II

**Air transport (IATA)**

UN/ID number: UN 1866  
Proper shipping name: UN 1866, Resin solution  
Class or division, Subsidiary risk: Class 3  
Packing Group: III  
Hazard label: Flamm. liquid  
Excepted Quantity Code: E1  
Passenger and Cargo Aircraft: Ltd.Qty.: Pack.Instr. Y344 - Max. Net Qty/Pkg. 10 L  
Passenger and Cargo Aircraft: Pack.Instr. 355 - Max. Net Qty/Pkg. 60 L  
Cargo Aircraft only: Pack.Instr. 366 - Max. Net Qty/Pkg. 220 L  
Special provisions: A3  
Emergency Response Guide-Code (ERG): 3L  
Remarks: Attention! IATA 3.3.3.1: single pack >= 30 L --> PG II

**15. Regulatory information**

**National regulations - U.S. Federal Regulations**

Methyl methacrylate: TSCA Inventory: listed; EPA flags T  
 TSCA HPVC: not listed  
 TSCA: listed - Flags: T  
 Carcinogen Status:  
   IARC Rating: Group 3  
   OSHA Carcinogen: not listed  
   NTP Rating: not listed  
 Clean Air Act:  
   Hazardous Air Pollutants: Code XOY  
   SOCMI Chemical: yes  
 Clean Water Act:  
   Hazardous Substances: RQ 1000 lbs.  
 Other Environmental Laws:  
   CERCLA: RQ 1000 lbs.  
   RCRA Hazardous Wastes: Code U162  
   RCRA Groundwater Monitoring: Methods 8015, 8240 / PQL 2, 5  
   SARA Title III Section 313, Toxic Release: Conc. 1.0% / Threshold Standard  
 NIOSH Recommendations:  
   Occupational Health Guideline: 0426

1,1'-(p-Tolylimino)dipropan-2-ol: TSCA Inventory: listed  
 TSCA HPVC: not listed  
 TSCA: listed

**National regulations - U.S. State Regulations**

Methyl methacrylate: Delaware Air Quality Management List:  
   DRQ: 1000 - RQ State: Federal Regulations Apply  
 Idaho Air Pollutant List:  
   Title 585; AAC: 20,5 - EL: 27,3 - OEL: 410 - Title 586: -  
 Massachusetts Haz. Substance Codes: 2,4,5,6 F8 F9  
 Main: HAP - 2000  
 Minnesota Haz. Substance:  
   Codes: AO - Ratings: 3.79 - Status: Air Pollutant. Title III. TRI.  
 New Jersey RTK Hazardous Substance:  
   DOT: 1247 - Sub No.: 1277  
 New York List of Hazardous Substances:  
   RQ-Air: 1000 - RQ-Land: 1  
   No Note Associated with this chemical  
 Pennsylvania Haz. Substance Code: E  
 Washington Air Contaminant: TWA: 100 ppm = 410 mg

**National regulations - Great Britain**

Hazchem-Code: •3YE

**16. Other information**

Text for labeling: Contains 40 - 70 % Methyl methacrylate, 0.1 - 1 % 1,1'-(p-Tolylimino)dipropan-2-ol. Safety data sheet available on request.

## SAFETY DATA SHEET

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

### 617H19 - ORTHOCRYL Lamination Resin

Material number 617H19

Revision date: 3/22/2018

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Page: 11 of 11

Hazard rating systems:



NFPA Hazard Rating:

Health: 2 (Moderate)

Fire: 3 (Serious)

Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 2 (Moderate)

Flammability: 3 (Serious)

Physical Hazard: 0 (Minimal)

Personal Protection: X = Consult your supervisor

JT Baker Storage Color Code: Red (Flammable Hazard)

HEALTH	2
FLAMMABILITY	3
PHYSICAL HAZARD	0
	X

Reason of change: Changes in section 1.3: Corporate headquarters

Date of first version: 10/26/1994

#### Department issuing data sheet

Contact person: see section 1: Dept. responsible for information

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.