

1. Product and company identification

Product identifier

Trade name: 617H119 - ORTHOCRYL Lamination Resin PRO

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: Physical state at 68 °F and 101.3 kPa: liquid

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.
 Store in a well-ventilated place. Keep cool.
 Dispose of contents/container to hazardous or special waste collection point.

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

Electrostatic charge.
 Watch for exothermic reactions with peroxides. Due to reducing substances and heavy metal ions polymerization with heat generation may occur.
 Potentially explosive mixtures may form if adequate ventilation is not provided.
 Special danger of slipping by leaking/spilling product.
 High concentrations of vapor or inhalation for an extended period may lead to paralysis of the central nervous system. Pulmonary edema is possible.
 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-Tolyimino) 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.
 Call a POISON CENTER/doctor if you feel unwell.

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.
 In case of skin irritation, consult a physician.

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

May cause respiratory irritation. Causes skin irritation.

May cause an allergic skin reaction.

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.

Air combined with vapors may form potentially explosive mixtures that are heavier than air.

Vapor may travel great distances and cause fire and backflashes.

Methyl methacrylate: Explosive mixtures with air may even form at room temperature.

In case of fire may be liberated: Organic crack products, carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters:

Wear self-contained positive pressure breathing apparatus and full firefighting protective clothing.

Additional information: Heating will lead to pressure increase: Danger of bursting and explosion. Cool exposed containers with water spray.

Move undamaged containers from immediate hazard area if it can be done safely.

In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.

Do not allow fire water to penetrate into surface or ground water.

Fire residuals and contaminated extinguishing water must be disposed of in accordance with the regulations of the local authorities.

6. Accidental release measures

Personal precautions: Remove all sources of ignition.

Provide adequate ventilation. Avoid breathing vapors.

When vapors form, use respiratory protection.

Wear suitable protective clothing. Do not get in eyes, on skin, or on clothing.

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).

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.
 Avoid breathing vapors.
 Do not get in eyes, on skin, or on clothing.

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 86 °F. 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.
 keep away from: reducing agent, amines, heavy metals, oxidizing agents, Alkalis

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

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 ³ ; 100 ppm
		USA: ACGIH: TWA	205 mg/m ³ ; 50 ppm
		USA: NIOSH: TWA	410 mg/m ³ ; 100 ppm
		USA: OSHA: TWA	410 mg/m ³ ; 100 ppm

Engineering controls

Provide adequate ventilation.
 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.
 Breakthrough time 60 min.

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:	Physical state at 68 °F and 101.3 kPa: liquid 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-% ((MMA)) UEL (Upper Explosive Limit): 12.50 Vol-% ((MMA))
Vapor pressure:	at 68 °F: (MMA) 38.7 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:	Not explosive. Vapors may form explosive mixtures with air.
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: Stable under recommended 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: UV-radiation/sunlight
- Incompatible materials: keep away from: reducing agent, amines, heavy metals, peroxides, oxidizing agents, mineral acids.
- Hazardous decomposition products:
 In case of fire may be liberated: Organic crack products, 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: The statements are derived from the properties of the single components. No toxicological data is available for the product as such.
 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:
 LD50 Rat, oral: > 5000 mg/kg (OECD 401)
 LC50 Rat, inhalative: 7093 ppm/4h = 29,8 mg/L
 LD50 Rabbit, dermal: >5000 mg/kg
 Irritant effect on the eye: Rabbit: Not an irritant (Draize)
 sensitization: Sensitivity testing among guinea pigs with and without adjuvants afforded both positive and negative results.
 Varying incidences of allergic reactions have been observed in humans. (Symptoms: Headache, eye irritations, skin problems)
 In-vitro Mutagenicity:
 Gene-mutations mammalian cells: inconclusive (OECD 476).
 Chromosomal aberrations mammalian cells: inconclusive.
 Bacterial mutagenicity: negative (Ames test, OECD 471) .
 In-vivo Mutagenicity:
 Chromosomal aberrations mammalian cells, rat: negative.
 Micronucleus test., Mouse: negative (OECD 474).
 Teratogenicity:
 Rat, inhalative: 2028 ppm, 6 - 15 d
 Product did not show any carcinogenous, mutagenous or teratogenic effects in animal experiments.
 Chronic toxicity:
 NOAEL (oral), rat: 124.1 mg/kg bw/d.
 NOAEC (inhalative), rat: 2028 mg/m³.
 Target organ: nose
 Symptoms: Damage of the mucous membranes in nose, throat and lungs. Degeneration of olfactory epithelia.
 Estimated lethal dose: 30g

Symptoms

Headache, drowsiness
 In case of inhalation: Mucous membrane irritation, Cough and shortage of breath.
 In case of ingestion:
 Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.
 After contact with skin: Irritant.
 May cause sensitization by skin contact.
 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: 69mg/L, 48h (OECD 202)
 NOEL Daphnia magna: 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

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



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

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

Further information

Attention! IMDG 2.3.2.3: single pack >= 30 L --> PG II
 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

Revision date: 3/22/2018

Version: 4

Language: en-US

Date of print: 5/24/2018

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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:

5/25/2012

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.