

1. Product and company identification

Product identifier

Trade name: 617H17 - ORTHOCRYL Flexible 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: Physical state at 68 °F and 101.3 kPa: liquid

Color: yellowish

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.
 Avoid breathing vapors.
 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.

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

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.

Relevant ingredients:

CAS No.	Designation	Content	Classification
CAS 80-62-6	Methyl methacrylate	30 - 60 %	Flammable Liquid - Category 2. Skin Irritation - Category 2. Sensitization - skin - Category 1. Specific Target Organ Toxicity (Single Exposure) - Category 3.
CAS 2082-81-7	Tetramethylene dimethacrylate	< 1	Sensitization - skin - Category 1.
CAS 103671-44-9	N,N-bis-(2-hydroxyethyl)-p-toluidine	< 1	Acute Toxicity - oral - Category 4. Eye Damage - Category 1.

4. First aid measures

General information: Take off immediately all contaminated clothing.
 Call a doctor if you feel unwell.

In case of inhalation: Move victim to fresh air; if necessary, provide artificial respiration or 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.

617H17 - ORTHOCRYL Flexible Resin

Material number 617H17

Page: 3 of 11

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. Never give anything by mouth to an unconscious person.

Most important symptoms/effects, acute and delayed

May cause respiratory irritation. Causes skin irritation.
May cause an allergic skin reaction.
The following symptoms may occur: Mucous membrane irritation, Cough and shortage of breath.
High concentrations of vapor or inhalation for an extended period may lead to paralysis of the central nervous system. Pulmonary edema is possible.

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. Vapor may travel great distances and cause fire and backflashes.
Information about Methyl methacrylate: Explosive mixtures with air may even form at room temperature.
In case of fire may be liberated: Carbon monoxide and carbon dioxide, Organic materials

Protective equipment and precautions for firefighters:

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

Additional information:

Heating will lead to pressure increase: Danger of bursting and explosion.
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.
In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.

6. Accidental release measures

Personal precautions: Eliminate all ignition sources if safe to do so.
Provide adequate ventilation. Wear appropriate protective equipment.
Avoid breathing vapors. When vapors form, use respiratory protection.
Avoid contact with the substance.
Keep unprotected people away.
Cordon off downwind area at risk and warn inhabitants.

Environmental precautions:

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

Danger of explosion!

In case of release, notify competent authorities.

Methods for clean-up:

Isolate leaked material using non-flammable absorption agent (e.g. sand, earth, vermiculit, diatomaceous earth) and collect it for disposal in appropriate containers in accordance with the local regulations (see section 13).

Beware of re-ignition. Thoroughly clean surrounding area.

In case of greater quantities: Collect mechanically (use only explosion-proof equipment when pumping out).

Additional information:

Take precautionary measures against static discharges.

In case of handling larger quantities: Use explosion-proof equipment and non-sparking tools/utensils.

Special danger of slipping by leaking/spilling product.

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 breathing vapors. When vapors form, use respiratory protection. Avoid contact with the substance.

Guarantee sufficient ventilation during and after use, in order to prevent vapour accumulation.

Precautions against fire and explosion:

Use only explosion-protected equipment/instruments. Do not weld.

Keep away from sources of ignition - No smoking.

Take precautionary measures against static discharges.

Explosion protection required.

In partially filled containers explosive mixtures may form.

Flammable mixtures may form in the air when product is heated above the flash point and/or during spraying.

Storage

Requirements for storerooms and containers:

Keep only in the original container at temperature not exceeding 86 °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.

Store containers in upright position.

Hints on joint storage:

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

Keep away from food, drink and animal feedingstuffs.

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: Wear suitable protective clothing.
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),
Breakthrough time ca. 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:
Do not breathe vapors.
Avoid contact with skin and eyes.
Separate storage of work clothes.
Take off immediately all contaminated clothing.
Wash hands before breaks and after work.
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
Color: yellowish
- 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: approx. 212 °F (1013 hPa)
- Flash point/flash point range: 50 °F (DIN 51755 (MMA))
- Evaporation rate: No data available
- Flammability: Highly flammable liquid and vapor.

617H17 - ORTHOCRYL Flexible Resin

Material number 617H17

Page: 6 of 11

Explosion limits:	LEL (Lower Explosion Limit) at 50 °F: (Methylmethacrylat) 2.10 Vol-% UEL (Upper Explosive Limit): (Methylmethacrylat) 12.50 Vol-%
Vapor pressure:	No data available
Vapor density:	No data available
Density:	at 68 °F: approx. 1 g/cm ³
Water solubility:	at 68 °F: not established
Partition coefficient: n-octanol/water:	at 68 °F: (OECD 107) 1.38 log P(o/w) (Methyl methacrylate) Based on the n-octanol/water partition coefficient significant accumulation in organisms is not expected.
Auto-ignition temperature:	No data available
Thermal decomposition:	No data available
Viscosity, dynamic:	at 68 °F: 1100 mPa*s (Brookfield)
Explosive properties:	Not explosive. Vapors may form explosive mixtures with air.
Ignition temperature:	806 °F (DIN 51794 (MMA))
Refraction index:	at 68 °F: approx. 40 hPa
Additional information:	Relative vapor density at 68 °F (air=1): 3.45 (Methylmethacrylat)

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. Heating will lead to pressure increase: Danger of bursting and explosion. Light-sensitive (Polymerisation!).
Conditions to avoid:	Keep away from heat sources, sparks and open flames. Protect from light and heat.
Incompatible materials:	Amines, ammonia, strong oxidizing agents. Danger of explosion with aldehydes. Contact with the following materials leads to a violent catalytic auto-reaction of the product: Organic peroxides (such as benzoyl-, acetyl-, lauroyl- and tertbutylhydro-peroxide), as well as combination such as azobis-iso-butyronitril, anionic liquid of sodium, ammonia and persulfate. 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: Carbon monoxide and carbon dioxide, Organic materials
Thermal decomposition:	No data available

11. Toxicological information

Toxicological tests

Toxicological effects:	<p>The statements are derived from the properties of the single components. No toxicological data is available for the product as such.</p> <p>Acute toxicity (oral): Lack of data.</p> <p>Acute toxicity (dermal): Lack of data.</p> <p>Acute toxicity (inhalative): Lack of data.</p> <p>Skin corrosion/irritation: Skin Irritation - Category 2 = Causes skin irritation.</p> <p>Serious eye damage/irritation: Lack of data.</p> <p>Sensitisation to the respiratory tract: Lack of data.</p> <p>Skin sensitisation: Sensitization - skin - Category 1 = May cause an allergic skin reaction.</p> <p>Germ cell mutagenicity/Genotoxicity: Lack of data.</p> <p>Carcinogenicity: Lack of data.</p> <p>Reproductive toxicity: Lack of data.</p> <p>Effects on or via lactation: Lack of data.</p> <p>Specific target organ toxicity (single exposure): Specific Target Organ Toxicity (Single Exposure) - Category 3 = May cause respiratory irritation.</p> <p>Specific target organ toxicity (repeated exposure): Lack of data.</p> <p>Aspiration hazard: Lack of data.</p>
Other information:	<p>Following information applies to the component Methyl methacrylate:</p> <p>LD50 Rat, oral: > 5000 mg/kg (OECD 401)</p> <p>LC50 Rat, inhalative: 7093 ppm/4h = 29,8 mg/L</p> <p>LD50 Rabbit, dermal: >5000 mg/kg</p> <p>Irritant effect on the eye: Rabbit: Not an irritant (Draize)</p> <p>sensitization: Sensitivity testing among guinea pigs with and without adjuvants afforded both positive and negative results.</p> <p>Varying incidences of allergic reactions have been observed in humans. (Symptoms: Headache, eye irritations, skin problems)</p> <p>In-vitro Mutagenicity:</p> <p>Gene-mutations mammalian cells: inconclusive (OECD 476).</p> <p>Chromosomal aberrations mammalian cells: inconclusive.</p> <p>Bacterial mutagenicity: negative (Ames test, OECD 471) .</p> <p>In-vivo Mutagenicity:</p> <p>Chromosomal aberrations mammalian cells, rat: negative.</p> <p>Micronucleus test:, Mouse: negative (OECD 474).</p> <p>Teratogenicity:</p> <p>Rat, inhalative: 2028 ppm, 6 - 15 d</p> <p>Product did not show any carcinogenous, mutagenous or teratogenic effects in animal experiments.</p> <p>Chronic toxicity:</p> <p>NOAEL (oral), rat: 124.1 mg/kg bw/d.</p> <p>NOAEC (inhalative), rat: 2028 mg/m³.</p> <p>Target organ: nose</p> <p>Symptoms: Damage of the mucous membranes in nose, throat and lungs. Degeneration of olfactory epithelia.</p> <p>Estimated lethal dose: 30g</p>

Symptoms

In case of inhalation: Cough and shortage of breath.

In case of ingestion:

Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.

After resorption of toxic quantities: CNS disorders, drowsiness, amyosthenia, coma, liver and kidney damage.

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/ISO 6341/EEC 84/449/V, C2)

Fish toxicity:

LC50 Oncorhynchus mykiss: >79 mg/L/96h (OECD 203/ISO 7346/EEC 84/449/V, C1)

NOEC Oncorhynchus mykiss: >40 mg/L/96h (OECD 203/ISO 7346/EEC 84/449/V, C1)

Mobility in soil

No data available

Persistence and degradability

Further details:

Following information applies to the component Methyl methacrylate:

Product is readily biodegradable. (OECD 301 C, 14d: 94%)

Abiotic degradation:

Hydrolysis (77 °F, pH 7): half-life time (DT50): 53 months.

Hydrolysis (77 °F, pH 11): half-life time (DT50): 2.4 h.

Air (Photo-oxidation, OH-) half-life time (DT50): 6.99 h.

Additional ecological information

Volatile organic compounds (VOC):

60 % by weight = 600 g/L

General information:

Do not allow to penetrate into soil, waterbodies or drains.

13. Disposal considerations

Product

Recommendation:

Special waste.

Incinerate 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: II
 Labels: 3
 Special provisions: 149, B52, IB2, T4, TP1, TP8
 Packaging – Exceptions: 150
 Packaging – Non-bulk: 173
 Packaging – Bulk: 242
 Quantity limitations – Passenger aircraft / rail: 5 L
 Quantity limitations – Cargo only: 60 L
 Vessel stowage – Location: B



Sea transport (IMDG)

UN number: UN 1866
 Proper shipping name: UN 1866, Resin solution
 Class or division, Subsidiary risk: Class 3, Subrisk -
 Packing Group: II
 EmS: F-E, S-E
 Special provisions: -
 Limited quantities: 5 L
 Excepted quantities: E2
 Contaminated packaging - Instructions: P001
 Contaminated packaging - Provisions: PP1
 IBC - Instructions: IBC02
 IBC - Provisions: -
 Tank instructions - IMO: -
 Tank instructions - UN: T4
 Tank instructions - Provisions: TP1, TP8
 Stowage and handling: Category B.
 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: II
 Hazard label: Flamm. liquid
 Excepted Quantity Code: E2
 Passenger and Cargo Aircraft: Ltd.Qty.: Pack.Instr. Y341 - Max. Net Qty/Pkg. 1 L
 Passenger and Cargo Aircraft: Pack.Instr. 353 - Max. Net Qty/Pkg. 5 L
 Cargo Aircraft only: Pack.Instr. 364 - Max. Net Qty/Pkg. 60 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

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 30 - 60 % Methyl methacrylate, < 1 Tetramethylene dimethacrylate, < 1 N,N-bis-(2-hydroxyethyl)-p-toluidine. Safety data sheet available on request.

SAFETY DATA SHEET

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

617H17 - ORTHOCRYL Flexible Resin

Material number 617H17

Revision date: 3/22/2018

Version: 9

Language: en-US

Date of print: 5/24/2018

Page: 11 of 11

Hazard rating systems:



NFPA Hazard Rating:

Health: 2 (Moderate)

Fire: 3 (Serious)

Reactivity: 1 (Slight)

HMIS Version III Rating:

Health: 2 (Moderate)

Flammability: 3 (Serious)

Physical Hazard: 1 (Slight)

Personal Protection: X = Consult your supervisor

HEALTH	2
FLAMMABILITY	3
PHYSICAL HAZARD	1
	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.