

617H17 - ORTHOCRYL Flexible Resin

Material number 617H17

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1. 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
Zip code, city: Salt Lake City, UT 84120
USA
WWW: www.ottobockus.com
Telephone: +1 (801) 956-2400
Telefax: +1 (801) 956-2401
Department 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 telephone 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. Hazard identification

Classification of the substance or mixture

Flammable Liquid - Category 2	Highly flammable liquid and vapor.
Skin Irritation - Category 2	Causes skin irritation.
Sensitization - skin - Category 1	May cause an allergic skin reaction.
Specific Target Organ Toxicity (Single Exposure) - Category 3	May cause respiratory irritation.

Label elements

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 mist/vapors/spray.
Wear protective gloves/protective clothing/eye protection.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/or shower.
Call a POISON CENTER/doctor if you feel unwell.

Store in a well-ventilated place. Keep cool.

Other hazards

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.
Information about Methyl methacrylate: Explosive mixtures with air may even form at room temperature.
Special danger of slipping by leaking/spilling product.

3. Composition/information on ingredients

Mixtures

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

Relevant ingredients:

CAS No.	Designation	Concentration	Classification
CAS 80-62-6	Methyl methacrylate	20 - 50 %	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 1B.
CAS -	p-Toluidine, ethoxylated	< 1 %	Acute Toxicity - oral - Category 4. Skin Irritation - Category 2. Eye Damage - Category 1. Sensitization - skin - Category 1. Aquatic toxicity - chronic - Category 3.

The actual concentration or concentration range is withheld as a trade secret.

4. First aid measures

General information: If medical advice is needed, have product container or label at hand. Take off contaminated clothing and wash it before reuse.

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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. In case of skin reactions, consult a physician.
After eye contact:	Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. 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 an allergic skin reaction. Causes skin irritation. May cause respiratory irritation. 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

Suitable (and unsuitable) extinguishing media

Suitable extinguishing media:

Foam, dry chemical powder, carbon dioxide

Extinguishing media which must not be used for safety reasons:

Full water jet

Specific hazards arising from the chemical

Highly flammable liquid and vapor. Concentrated vapors are heavier than air. Vapors may proceed on the ground over 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: Organic materials, sulphur oxides, 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 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.

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6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Eliminate all ignition sources if safe to do so. Plug leak if safely possible. Provide adequate ventilation.
Wear appropriate protective equipment. Take off contaminated clothing and wash it before reuse.
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 and material for containment and cleaning up

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.
Special danger of slipping by leaking/spilling product.

7. Handling and storage

Precautions for safe 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 vapor accumulation.
Take off contaminated clothing and wash it before reuse. Do not eat, drink or smoke when using this product.
Work place should be equipped with a shower and an eye rinsing apparatus.

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.
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.

Conditions for safe storage, including any incompatibilities

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.
Store containers in upright position.
Maximum storage temperature: 95 °F

Hints on joint storage:

Keep away from food, drink and animal feedingstuffs.
Keep away from: Peroxides, amines, sulphur compounds, heavy metals, alkali compounds, reducing agents, oxidizing agents

Further details:

Possibility of hazardous reactions: Polymerization along with heat production.

8. Exposure controls/personal protection

Control parameters

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: IDLH: TWA	1,000 ppm
		USA: NIOSH: TWA	410 mg/m ³ ; 100 ppm
		USA: OSHA: TWA	410 mg/m ³ ; 100 ppm

Appropriate engineering controls

Provide for good ventilation or exhaust system or work with completely self-contained equipment.

Personal protection equipment (PPE)

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.
The filter class must be suitable for the maximum contaminant concentration (gas/vapor/aerosol/particulates) that may arise when handling the product.

Hand protection:

Protective gloves according to OSHA Standard - 29 CFR: 1910.138.
Glove material: butyl caoutchouc (butyl rubber) - Layer thickness 0.3 mm
Breakthrough time: ca. 60 min.
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection:

Tightly sealed goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010.

Body protection:

Wear suitable protective clothing.
When handling larger quantities: face protection, rubber boots and rubber apron.

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General hygiene considerations:

- Do not breathe vapors.
- Avoid contact with skin and eyes.
- Separate storage of work clothes.
- Wash hands before breaks and after work.
- Keep away from sources of ignition - No smoking.
- Take off contaminated clothing and wash it before reuse.
- When using do not eat or drink.
- Work place should be equipped with a shower and an eye rinsing apparatus.

Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state at 68 °F and 101.3 kPa	liquid
Color:	yellow
Odor:	Ester-like
Odor threshold:	No data available
Melting point/freezing point:	-54.4 °F (Methyl methacrylate)
Initial boiling point and boiling range:	approx. 212 °F (1013 hPa)
Flammability:	Highly flammable liquid and vapor.
Explosion limits:	LEL (Lower Explosion Limit): at 10,5 °C: 2.10 Vol-% (Methyl methacrylate) UEL (Upper Explosive Limit): 12.50 Vol-% (Methyl methacrylate)
Flash point/flash point range:	50 °F (Methyl methacrylate)
Evaporation rate:	No data available
Auto-ignition temperature:	815 °F (Methyl methacrylate)
Decomposition temperature:	No data available
pH:	Not applicable. (The product is nonpolar/aprotic.)
Dynamic viscosity:	at 68 °F: approx. 1,100 mPa*s (Brookfield)
Viscosity, kinematic:	at 68 °F: 1,100 mm²/s (calculated)
Water solubility:	at 68 °F: approx. 16 g/L (estimated)
Partition coefficient: n-octanol/water:	No data available
Vapor pressure:	at 68 °F: approx. 40 hPa
Density:	at 68 °F: approx. 1 g/mL
Vapor density:	at 68 °F: >= 1
Particle characteristics:	Not applicable

Additional information

Explosive properties:	Not explosive. Vapors may form explosive mixtures with air.
Ignition temperature:	806 °F (Methyl methacrylate)

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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:** Peroxides, amines, sulphur compounds, heavy metals, alkali compounds, reducing agents, oxidizing agents
- Hazardous decomposition products:**
No decomposition when used properly.

11. Toxicological information

Information on toxicological effects

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): Based on available data, the classification criteria are not met.

ATEmix: > 5,000 mg/kg

Acute toxicity (dermal): Lack of data.

ATEmix: > 5,000 mg/kg

Acute toxicity (inhalative): Lack of data.

ATEmix, vapor: >30 mg/L

Skin corrosion/irritation: Skin Irritation - Category 2 = Causes skin irritation.

Serious eye damage/irritation: Based on available data, the classification criteria are not met.

Sensitisation to the respiratory tract: Lack of data.

Skin sensitisation: Sensitization - skin - Category 1 = May cause an allergic skin reaction.

Germ cell mutagenicity/Genotoxicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Based on available data, the classification criteria are not met.

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): Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

Other information: Information about Methyl methacrylate (CAS No. 80-62-6):

LD50 Rat, oral: > 5,000 mg/kg (OECD 401)

LC50 Rat, inhalative: 7,093 ppm/4h = 29.8 mg/L

LD50 Rabbit, dermal: > 5,000 mg/kg

Information about Tetramethylene dimethacrylate (CAS No. 2082-81-7):

LD50 Rat, oral: > 5,000 mg/kg

LD50 Rabbit, dermal: > 3,000 mg/kg

Information about p-Toluidine, ethoxylated (EC 911-490-9):

LD50 Rat, oral: 619 mg/kg

LD50 Rat, dermal: > 2,000 mg/kg

For carcinogenic effects:

IARC Rating: Group 3

OSHA Carcinogen: not listed

NTP Rating: not listed

Symptoms

In case of prolonged exposure: Headache, drowsiness, fatigue
In case of inhalation:
Mucous membrane irritation, cough and shortage of breath, dizziness, Disorientation
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: Upon direct contact with eyes may cause burning, tearing, redness.

12. Ecological information

Ecotoxicity

Aquatic toxicity:

Information about Methyl methacrylate (CAS No. 80-62-6):
Algae toxicity:
EC50 Selenastrum capricornutum (green algae): > 100 mg/L/72h (OECD 201)
NOEC Selenastrum capricornutum (green algae): > 100 mg/L/72h (OECD 201)
Daphnia toxicity:
EC50 Daphnia magna (Big water flea): 69 mg/L/48h (OECD 202)
NOEC Daphnia magna (Big water flea): 37 mg/L/21d (OECD 202)
Fish toxicity:
LC50: > 100 mg/L/96h (OECD 203, Data obtained by expert judgement.)
Information about Tetramethylene dimethacrylate (CAS No. 2082-81-7):
Algae toxicity:
EC50 Desmodesmus subspicatus (green algae): 9.79 mg/L/72h (OECD 201)
Daphnia toxicity:
EC10 Daphnia magna (Big water flea): 7.51 mg/L/21d (OECD 211)
Fish toxicity:
LC50 Leuciscus idus melanotus: 32.5 mg/L/48h (By analogy)
Information about p-Toluidine, ethoxylated (EC 911-490-9):
Algae toxicity:
EC50 Pseudokirchneriella subcapitata (green algae): > 100 mg/L/72h (OECD 201)
Daphnia toxicity:
EC50 Daphnia magna (Big water flea): 48 mg/L/48h (OECD 202)
Fish toxicity:
LC50 Cyprinus carpio (Common Carp): > 100 mg/L/96h (OECD 203)

Effects in sewage plants:

Information about Methyl methacrylate (CAS No. 80-62-6):
EC3 Pseudomonas putida: 100 mg/L/16h (cell multiplication inhibition test)
Information about Tetramethylene dimethacrylate (CAS No. 2082-81-7):
NOEC activated sludge: 20 mg/L
Information about p-Toluidine, ethoxylated (EC 911-490-9):
EC50 activated sludge: > 1,000 mg/L/3h

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Persistence and degradability

Further details: Biodegradability:
Information about Methyl methacrylate (CAS No. 80-62-6): 94 %/14 d (OECD 301 C), easily bio-degradable
Information about Tetramethylene dimethacrylate (CAS No. 2082-81-7): 84 %/28 d (OECD 310), easily bio-degradable
Information about p-Toluidine, ethoxylated (EC 911-490-9): < 2%/28 d (OECD 301 B), not easily bio-degradable

Bioaccumulative potential

Partition coefficient: n-octanol/water:
No data available

Mobility in soil

No data available

Other adverse effects

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

13. Disposal considerations**Waste treatment methods****Product**

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

Package

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.
Handle empty containers with care. Incineration may cause explosion.

14. Transport information**UN number**

DOT: UN1866
IMDG, IATA-DGR: UN 1866

UN proper shipping name

DOT, IMDG, IATA-DGR: UN 1866, RESIN SOLUTION

Transport hazard class(es)

DOT: 3
IMDG: Class 3, Subrisk -
IATA-DGR: Class 3



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Packing group

DOT, IMDG, IATA-DGR: II

Environmental hazards

Marine pollutant: no

Transport in bulk according to IMO instruments

No data available

Special precautions for user

USA: Department of Transportation (DOT)

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)

EmS: F-E, S-E
Special Provisions: -
Limited quantities: 5 L
Excepted quantities: E2
Package - Instructions: P001
Package - 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: For packages <= 30 litres: PG III (IMDG 2.3.2.2)

Air transport (IATA)

Proper shipping name: UN 1866, RESIN SOLUTION
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: For packages <= 30 litres: PG III (IATA 3.3.3.1)

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15. Regulatory information

National regulations - U.S. Federal Regulations

Product: TSCA: All ingredients are listed or exempt from listing.

Methyl methacrylate: Carcinogen Status: IARC Rating: Group 3
OSHA Carcinogen: not listed
NTP Rating: not listed

Clean Air Act:
CAA Hazardous Air Pollutants: yes
CAA SOCM Chemical: yes

Clean Water Act:
CWA Hazardous Substances: Category C; RQ 1000.0 lbs

Other Environmental Laws:
CERCLA: RQ 1000 lbs.
RCRA Hazardous Wastes: Waste Code U162
RCRA Groundwater Monitoring: listed
SARA Title III, Section 313, Toxic Release: NPFAS; De Minimis <=1.0 %;
Thresholds 25000/10000 lbs

NIOSH Recommendations:
Occupational Health Guideline: 0426

National regulations - U.S. State Regulations

Methyl methacrylate: New York Right-To-Know: listed

Further regulations, limitations and legal requirements

No data available

16. Other information

Uses advised against: Cosmetics.
Do not use for products which come into direct contact with the skin. (Liquid)

Text for labeling: Contains 20 - 50 % Methyl methacrylate, < 1 % Tetramethylene dimethacrylate, < 1 % p-Toluidine, ethoxylated.

Revision date: 11/28/2025

Date of first version: 10/26/1994

Reason of change: General revision: Safety Data Sheet according to HCS 2024 (29 CFR 1910.1200)

Classification procedure: Physical hazards: on basis of test data
Health hazards: calculation method

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

Abbreviations and acronyms:

Acute Toxicity: Acute toxicity
Aquatic toxicity - chronic: Hazardous to the aquatic environment - chronic
AS/NZS: Australian Standards/New Zealand Standards
ATEmix: Acute Toxicity Estimate of mixture
BEL: Biological exposure index
CAS: Chemical Abstracts Service
CFR: Code of Federal Regulations
CLP: Classification, Labelling and Packaging
CNS: Central Nervous System
DMEL: Derived minimal effect level
DNEL: Derived no-effect level
DOT: Department of Transportation's Safety Regulations (USA)
EC: European Community
EC50: Effective Concentration 50%
EmS: Emergency Response Procedures for Ships Carrying Dangerous Goods
EN: European Standard
EQ: Excepted quantities
Eye Damage: Eye damage
Flammable Liquid: Flammable liquid
IATA: International Air Transport Association
IATA-DGR: International Air Transport Association – Dangerous Goods Regulations
IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
IMDG Code: International Maritime Dangerous Goods Code
IMO: International Maritime Organization
LC50: Median lethal concentration
LD50: Lethal dose 50%
LEL: Lower Explosion Limit
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
MFSU: Manufacture, formulation, supply and use
NOEC: No Observed Effect Concentration
OECD: Organisation for Economic Co-operation and Development
OEL: Occupational Exposure Limit Value
OSHA: Occupational Safety and Health Administration
PBT: Persistent, bioaccumulative and toxic
PNEC: Predicted no-effect concentration
Sensitization - skin: Skin sensitisation
Skin Irritation: Skin irritation
STOT SE: Specific target organ toxicity - single exposure
TLV: Threshold Limit Value
TRGS: Technical Rules for Hazardous Substances
UN: United Nations
vPvB: Very persistent and very bioaccumulative
WEL: Workplace Exposure Limit

Department issuing data sheet

Contact person: see section 1: Department 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.