

1. Product and company identification

Product identifier

Trade name: 617H17 - ORTHOCRYL Flexible Resin

This safety data sheet pertains to the following products:

617H17=0.900 E

617H17=2.300 E

617H17=25 E

617H17=4.600 E

Recommended use and restrictions on use

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

Initial supplier identifier

Company name: Otto Bock HealthCare Canada Ltd.

Street/POB-No.: 5470 Harvester Road

Postal Code, city: Burlington, ON L7L 5N5, CA
Canada

WWW: www.ottobock.ca

E-mail: info.canada@ottobock.com

Telephone: (800) 665-3327

Telefax: (800) 463-3659

Department responsible for information:

Mark Agro, Telephone: (800) 665-3327 (9 am - 5 pm)

Additional information:

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

Emergency phone number

COLLECT, Telephone: (613) 996-6666

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 20 °C and 101.3 kPa: liquid

Color: yellow

Odor: Ester-like

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

Regulatory status

This material is considered hazardous by the WHMIS 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.
Information about Methyl methacrylate: Explosive mixtures with air may even form at room temperature.
Special danger of slipping by leaking/spilling product.
see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterisation: 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 2. Skin Irritation 2. Sensitization - skin 1. Specific Target Organ Toxicity (Single Exposure) 3.
CAS 2082-81-7	Tetramethylene dimethacrylate	< 1 %	Sensitization - skin 1.
CAS -	p-Toluidine, ethoxylated	< 1 %	Acute Toxicity 4 (oral). Skin Irritation 2. Eye Damage 1. Sensitization - skin 1. Aquatic toxicity - chronic 3.

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.

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 and effects, both 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

Flash point/flash point range:

10 °C (Methyl methacrylate)

Auto-ignition temperature: 435 °C (Methyl methacrylate)

Suitable extinguishing media:

Foam, extinguishing 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

Special protective equipment and precautions for fire-fighters:

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.

6. Accidental release measures

Personal precautions:	<p>Eliminate all ignition sources if safe to do so. Plug leak if safely possible. Provide adequate ventilation.</p> <p>Wear appropriate protective equipment. Take off contaminated clothing and wash it before reuse.</p> <p>Avoid breathing vapors. When vapors form, use respiratory protection. Avoid contact with the substance.</p> <p>Keep unprotected people away.</p> <p>Cordon off downwind area at risk and warn inhabitants.</p>
Environmental precautions:	<p>Do not allow to enter into ground-water, surface water or drains.</p> <p>Danger of explosion!</p> <p>In case of release, notify competent authorities.</p>
Methods for clean-up:	<p>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.</p> <p>In case of greater quantities: Collect mechanically (use only explosion-proof equipment when pumping out).</p>
Additional information:	<p>Use explosion-proof equipment and non-sparking tools/utensils.</p> <p>Special danger of slipping by leaking/spilling product.</p>

7. Handling and storage

Handling

Advices on safe handling:	<p>Provide adequate ventilation, and local exhaust as needed.</p> <p>Provide room air exhaust at ground level. Concentrated vapors are heavier than air.</p> <p>Wear appropriate protective equipment. Avoid breathing vapors. When vapors form, use respiratory protection. Avoid contact with the substance.</p> <p>Guarantee sufficient ventilation during and after use, in order to prevent vapour accumulation.</p> <p>Take off contaminated clothing and wash it before reuse. Do not eat, drink or smoke when using this product.</p> <p>Work place should be equipped with a shower and an eye rinsing apparatus.</p>
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Precautions against fire and explosion:	<p>Use only explosion-protected equipment/instruments. Do not weld.</p> <p>Keep away from sources of ignition - No smoking.</p> <p>Take precautionary measures against static discharges.</p> <p>In partially filled containers explosive mixtures may form.</p> <p>Flammable mixtures may form in the air when product is heated above the flash point and/or during spraying.</p>
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Storage

Requirements for storerooms and containers:	<p>Keep only in the original container at temperature not exceeding 35 °C.</p> <p>Keep container tightly closed. Protect from light.</p> <p>Because oxygen (air) is necessary to stabilize product, fill container only to 90% of capacity.</p> <p>Provide adequate oxygen (air) circulation for large containers to ensure product stability.</p> <p>Store containers in upright position.</p> <p>Maximum storage temperature: 35 °C</p>
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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

Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
80-62-6	Methyl methacrylate	Canada: OEL 15 min	410 mg/m ³ ; 100 ppm
		Canada: OEL 8 hour	205 mg/m ³ ; 50 ppm
		Canada: OEL STEL	100 ppm
		Canada: OEL TWA	50 ppm
		Canada: VECD	100 ppm
		Canada: VEMP	50 ppm

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: 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) - Layer thickness 0.3 mm
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.
The filter class must be suitable for the maximum contaminant concentration (gas/vapor/aerosol/particulates) that may arise when handling the product.

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

Appearance:	Physical state at 20 °C and 101.3 kPa: liquid Color: yellow
Odor:	Ester-like
Odor threshold:	No data available
pH:	Not applicable. (The product is nonpolar/aprotic.)
Melting point/freezing point:	-48 °C (Methyl methacrylate)
Initial boiling point and boiling range:	approx. 100 °C (1013 hPa)
Flash point/flash point range:	10 °C (Methyl methacrylate)
Evaporation rate:	No data available
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)
Vapor pressure:	at 20 °C: approx. 40 hPa
Vapor density:	at 20 °C: >= 1
Density:	at 20 °C: approx. 1 g/mL
Water solubility:	at 20 °C: approx. 16 g/L (estimated)
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	435 °C (Methyl methacrylate)
Thermal decomposition:	No data available
Viscosity, dynamic:	at 20 °C: approx. 1,100 mPa*s (Brookfield)
Viscosity, kinematic:	at 20 °C: 1,100 mm²/s (calculated)
Explosive properties:	Not explosive. Vapors may form explosive mixtures with air.
Ignition temperature:	430 °C (Methyl methacrylate)

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.

Thermal decomposition:

No data available

11. Toxicological information

Toxicological tests

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 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 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) 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

Mobility in soil

No data available

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

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.

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

ADR/RID, IMDG, IATA-DGR:

UN 1866

UN proper shipping name

ADR/RID, IMDG, IATA-DGR:

UN 1866, RESIN SOLUTION

Transport hazard class(es)

ADR/RID:

Class 3, Code: F1

IMDG:

Class 3, Subrisk -

IATA-DGR:

Class 3



Packing group

ADR/RID, IMDG, IATA-DGR:

II

Environmental hazards

Marine pollutant:

no

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No data available

Canada: Transportation of Dangerous Goods (TDG)

UN Number: UN1866
Shipping name: UN 1866, resin solution
TDG class: 3
Packing group: III
Explosive limit and limited quantity index: 5 L
Passenger carrying road or rail index: 60 L

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
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)

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: For packages < = 30 litres: PG III (IATA 3.3.3.1)

15. Regulatory information

National regulations - Canada

Product: DSL: All ingredients are listed or exempt from listing.
Methyl methacrylate: DSL: listed
Tetramethylene dimethacrylate: DSL: listed

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.

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

Classification procedure:

Physical hazards: on basis of test data

Health hazards: calculation method

Abbreviations and acronyms:

Acute Toxicity: Acute toxicity

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

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

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

RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail

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

WHMIS: Workplace Hazardous Materials Information System

Reason of change: Changes in section 8: Occupational exposure limit values

Date of first version: 26/10/1994

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.