1. Product and company identification

Product identifier

Trade name: 617H21 - ORTHOCRYL Sealing Resin

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

General use: for orthopedic procedures Lamination Resin
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

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

see section 11: Toxicological information

3. Composition / Information on ingredients

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

Hazardous ingredients:

CAS No.	Designation	Content	Classification
CAS 80-62-6	Methyl methacrylate	60 - 100 %	Flammable Liquid - Category 2. Skin Irritation - Category 2. Sensitization - skin - Category 1. Specific Target Organ Toxicity (Single Exposure) - Category 3.
CAS 38668-48-3	N,N-bis-(2-hydroxypropyl) -p-toluidine	0.1 - 1 %	Acute Toxicity - oral - Category 3. Eye Damage - Category 1. Aquatic toxicity - chronic - Category 3.
CAS 123-81-9	Ethylen-di(S-thioacetate)	0.1 - 1 %	Acute Toxicity - oral - Category 4. Acute Toxicity - dermal - Category 4. Acute Toxicity - inhalative - Category 4. Aquatic toxicity - chronic - Category 2.

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 mouth-to-mouth resuscitation 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

Causes skin irritation. May cause an allergic skin reaction. May cause respiratory irritation.
In case of prolonged exposure: Headache, drowsiness.

Information to physician

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range:

Methyl acrylate: 50 °F

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 protective equipment. Avoid breathing vapors.
When vapors form, use respiratory protection. Avoid contact with skin and eyes.

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.

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

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. Avoid contact with skin and eyes. Do not breathe vapors. Wear protective equipment.

Precautions against fire and explosion:

Eliminate all ignition sources if safe to do so. Keep away from sources of ignition. - No smoking.
Take precautionary measures against static discharges.
Air combined with vapors may form potentially explosive mixtures that are heavier than air. Vapor may travel great distances and cause fire and backflashes.
Use only explosion-proof equipment.

Storage

Requirements for storerooms and containers:

Keep only in the original container at temperature not exceeding 77 °F.
Keep container tightly closed. Protect from light.
Because oxygen (air) is necessary to stabilize product, fill container only to 90% of capacity.

Hints on joint storage: Do not store together with organic peroxides, ammonia or persulphates. Watch for exothermic reactions with peroxides.
Due to reducing substances 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/m³; 100 ppm
		USA: ACGIH: TWA	205 mg/m³; 50 ppm
		USA: NIOSH: TWA	410 mg/m³; 100 ppm
		USA: OSHA: TWA	410 mg/m³; 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 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: handling larger quantities: Face mask, chemical-resistant boots and apron

Protective gloves according to OSHA Standard - 29 CFR: 1910.138.

Glove material: butyl caoutchouc (butyl rubber)
Layer thickness: 0.7 mm
Breakthrough time approx. 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:	Form: liquid Color: colorless
Odor:	ester-like
Odor threshold:	no data available
pH value:	not applicable
Melting point/freezing point:	no data available
Initial boiling point and boiling range:	212.9 °F (1013 hPa)
Flash point/flash point range:	Methyl acrylate: 50 °F
Evaporation rate:	no data available
Flammability:	no data available
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: 40 hPa at 122 °F: 159 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
Ignition temperature:	Methyl acrylate: 806 °F
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 normaly delivered in a stable state. However, if shelf life and/or recommended storage temperature are exceeded to a large degreee, 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: Strong oxidizing agents, sulphur compounds, amines, reducing agents and alkali compounds.
Do not store together with organic peroxides, ammonia or persulphates. 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: Methyl methacrylate > 5000 mg/kg
LD50 Rabbit, dermal: Methyl methacrylate > 5000 mg/kg
LC50 Rat, inhalative: Methyl methacrylate 29.8 mg/l

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.

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: 20-200 mg/kg

Symptoms

In case of inhalation:
Information about Methyl methacrylate: Mucous membrane irritation, Cough and shortage of breath.
In case of ingestion:
Information about Methyl methacrylate: Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.
After contact with skin:
Information about Ethylene di(S-thioacetate): Danger of cutaneous absorption.
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): 69 mg/L/48h (OECD 202/ISO 6341/EEC 84/449/V, C2)
NOEC Daphnia magna (Big water flea): 37 mg/L/21 d (OECD 202)

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

Information about Ethylene di(S-thioacetate): not readily biodegradable (according to OECD criteria).

Additional ecological information

Volatile organic compounds (VOC):
67 % by weight = 670 g/L

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

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 numbers:	UN1866
Proper shipping name:	UN 1866, resin solution
DOT hazard class or division:	3
PG:	III
Label codes:	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
IMDG:	Class 3, Subrisk -
Packing Group:	III
EmS:	F-E, S-E
Special provisions:	223, 955
Limited quantities:	5 L
EQ:	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

Air transport (IATA)

UN/ID number:	UN 1866
Proper shipping name:	UN 1866, Resin solution
ICAO/IATA:	Class 3
PG:	III
Hazard:	Flamm. liquid
EQ:	E1
Passenger Ltd.Qty.:	Pack.Instr. Y344 - Max. Net Qty/Pkg. 10 L
Passenger:	Pack.Instr. 355 - Max. Net Qty/Pkg. 60 L
Cargo:	Pack.Instr. 366 - Max. Net Qty/Pkg. 220 L
Special Provisioning:	A3
ERG:	3L

15. Regulatory information

National regulations - U.S. Federal Regulations

Product:	TSCA: All components of this product are on the TSCA inventory or are exempt from TSCA Inventory requirements.
Methyl methacrylate:	TSCA: listed - Flags: T TSCA Inventory: listed; EPA flags T TSCA HPVC: not listed Carcinogen Status: IARC Rating: Group 3 OSHA Carcinogen: not listed NTP Rating: not listed Clean Air Act: Hazardous Air Pollutants: Code XOV 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
N,N-bis-(2-hydroxypropyl)-p-toluidine:	TSCA: listed TSCA Inventory: listed TSCA HPVC: not listed
Ethylen-di(S-thioacetate):	TSCA: listed

National regulations - U.S. State Regulations

California Prop 65 List: None

National regulations - Canada

All components of this product are listed on Canada's DSL and Ingredient Disclosure Lists.
Classification: B2, D2B

This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

National regulations - Great Britain

Hazchem-Code: •3YE

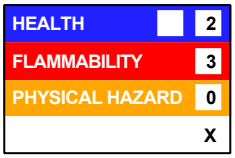
16. Other information

Text for labeling: Contains 60 - 100 % Methyl methacrylate, 0.1 - 1 % N,N-bis-(2-hydroxypropyl)-p-toluidine, 0.1 - 1 % Ethylen-di(S-thioacetate). Safety data sheet available on request.

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



Reason of change: Changes in section 1: Address
Changes in section 7: General revision

Date of first version: 9/4/1998

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.