1. Product and company identification

Product identifier

Trade name: 617H51 - ORTHOCRYL Extra 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: Form: 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.
Use only outdoors or in a well-ventilated area.
Wear protective gloves/protective clothing/eye protection/face protection.
IF ON SKIN: Wash with plenty of water/soap.
Call a doctor if you feel unwell.
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

Vapors irritate eyes and respiratory system. Pulmonary edema is possible.
High concentrations of vapor or inhalation for an extended period may lead to paralysis of the central nervous system.

Potentially explosive mixtures may form if adequate ventilation is not provided.
Special danger of slipping by leaking/spilling product.
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	15 - 40 %	Flammable Liquid - Category 2. Skin Irritation - Category 2. Sensitization - skin - Category 1. Specific Target Organ Toxicity (Single Exposure) - Category 3.
CAS 39670-09-2	Ethylentriglycolmethacrylate	5 - 10 %	Skin Irritation - Category 2. Eye Irritation - Category 2A. Specific Target Organ Toxicity (Single Exposure) - 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; 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.

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.
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.
In case of prolonged or frequent exposure eye irritation may occur.

Information to physician

Monitor breathing.
Treat symptomatically.
If spray contacts eyes, immediately and thoroughly flush eyes with water; profitable is the application of isotonic eye rinse.
On irritation of the respiratory system use an aerosol dispenser and treat with 5 doses of dexamethasone aerosol (e.g. Auxiloson, Thomae) every 10 minutes until symptoms cease.
Estimated lethal dose: 30g

5. Fire fighting measures

Flash point/flash point range:
(Methylmethacrylat) 50 °F (DIN 51755)

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. Flammable mixtures may form in the air when product is heated above the flash point and/or during spraying.
In case of fire may be liberated: Carbon monoxide and carbon dioxide

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 suitable protective clothing.
When vapors form, use respiratory protection.
Avoid contact with skin and eyes.
Wear appropriate protective equipment. Avoid breathing vapors.
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: In case of greater quantities: Collect mechanically (use only explosion-proof equipment when pumping out).
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.

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.

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

Precautions against fire and explosion:
Keep away from sources of ignition - No smoking.
Take precautionary measures against static discharges.
In case of fire, cool endangered containers with water.
Flammable mixtures may form in the air when product is heated above the flash point and/or during spraying.
Use only explosion-proof equipment. Do not weld.

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.

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/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

Engineering controls

Make sure there is sufficient air exchange and / or that working rooms are air suctioned.
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), Nitrile rubber
Breakthrough time: >480 min.
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

In permeation tests, gloves made of butyl rubber or nitrile rubber showed better results than those made of latex or natural rubber. Protective gloves must be changed regularly, in particular following intensive contact with the product. A suitable type of glove must be chosen for each work place.

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.
Take off immediately all contaminated clothing. Separate storage of work clothes.
Wash hands before breaks and after work.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Form: liquid Color: yellowish
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:	approx. 212 °F (1.013 hPa)
Flash point/flash point range:	(Methylmethacrylat) 50 °F (DIN 51755)
Evaporation rate:	No data available
Flammability:	Highly flammable liquid and vapor.

Explosion limits:	LEL (Lower Explosion Limit): (Methylmethacrylat) 2.10 Vol-% UEL (Upper Explosive Limit): (Methylmethacrylat) 12.50 Vol-%
Vapor pressure:	at 68 °F: approx. 47 hPa at 122 °F: 159 hPa (Methyl methacrylate)
Vapor density:	No data available
Density:	at 68 °F: approx. 1.02 g/mL
Solubility:	soluble in acetone and ethyl acetate
Water solubility:	at 68 °F: approx. 16 g/L
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	No adverse effects known to this day, when properly handled.
Viscosity, dynamic:	at 68 °F: (dynamic) 1500 mPa*s (Brookfield)
Explosive properties:	Not explosive. Vapors may form explosive mixtures with air.
Ignition temperature:	(Methylmethacrylat) 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.
Flammable mixtures may form in the air when product is heated above the flash point and/or during spraying.

Chemical stability:
Stable under recommended storage conditions.
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.

Possibility of hazardous reactions
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 and heat.

Incompatible materials:
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

Thermal decomposition:
No adverse effects known to this day, when properly handled.

11. Toxicological information

Toxicological tests

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.

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:

No toxicological data is available for the product as such.

Following information applies to the component Methyl methacrylate:
LD50 Rat, oral: >5000 mg/kg
LC50 Rat, inhalative: 29,8 mg/l/4h
LD50 Rabbit, dermal: >5000 mg/kg
Skin irritation, Rabbit, 24h: Not an irritant (FDA, Draize).
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.
May cause sensitization by skin contact. Varying incidences of allergic reactions have been observed in humans. (Symptoms: Headache, eye irritations, skin problems)
Mutagenicity:
not a mutagen (Dose 10000 µg/plate (Salmonella typhimurium, Ames-Test)
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)
Product did not show any carcinogenous, mutagenous or teratogenic effects in animal experiments. (Teratogenicity: Rat, inhalative: 2028 ppm, 6 - 15 d)
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 ethyl triglycol methacrylate:
LD50 Rat, oral: >5000 mg/kg Stable under recommended storage conditions.

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: In case of prolonged or frequent exposure eye irritation may occur.

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

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:	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, Subsidary 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, Subsidary 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

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 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

Ethylentriglycolmethacrylate: 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

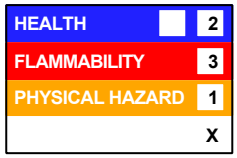
16. Other information

Text for labeling: Contains 15 - 40 % Methyl methacrylate, 5 - 10 % Ethylentriglycolmethacrylate. Safety data sheet available on request.

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



Reason of change: Changes in section 1.3: Corporate headquarters

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.