

1. Product and company identification

Product identifier

Trade name: 617H255 - C-Orthocryl Skinguard

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

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; Aquatic toxicity - acute - Category 1; Aquatic toxicity - chronic - Category 1;

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.
 Very toxic to aquatic life with long lasting effects.

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.
- Avoid release to the environment.
- 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

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	40 - 70 %	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.
CAS 3380-34-5	Triclosan	0.25 - 1 %	Skin Irritation - Category 2. Eye Irritation - Category 2A. Aquatic toxicity - acute - Category 1. Aquatic toxicity - chronic - Category 1.

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. Take off immediately all contaminated clothing and wash it before reuse. 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:

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. Potential health effects.

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.

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:

Eliminate all ignition sources if safe to do so.

Provide adequate ventilation. Avoid breathing vapors.

Wear protective equipment. Avoid contact with skin, eyes, and clothing.

When vapors form, use respiratory protection.

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.

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.
 Keep container tightly closed. Avoid breathing vapors.
 Wear protective equipment. Take off immediately all contaminated clothing and wash it before reuse.

Precautions against fire and explosion:
 Keep away from sources of ignition. - No smoking.
 Take precautionary measures against static discharges.
 Use only explosion-proof equipment.
 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.
 Concentrated vapors are heavier than air.

Storage

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.
 Provide room air exhaust at ground level.

Hints on joint storage: Do not store together with organic peroxides, ammonia or persulphates.

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 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: 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 0,7 mm.
 Breakthrough time <480 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, eyes, and clothing.
 Wash hands before breaks and after work.
 Separate storage of work clothes.
 Take off immediately all contaminated clothing and wash it before reuse.
 Keep away from sources of ignition. - No smoking.
 Safety shower and eye wash station should be easily accessible to the work area.

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:	no data available
Melting point/freezing point:	no data available
Initial boiling point and boiling range:	212.9 °F (1013 hPa (MMA))
Flash point/flash point range:	50 °F (DIN 51755 (MMA))
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: (MMA) 47 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.
Ignition temperature:	806 °F (DIN 51794 (MMA))
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.

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Chemical stability: Product is stable under normal storage conditions.
Stabilization required by: oxygen.

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.

Conditions to avoid: Keep away from heat sources, sparks and open flames.
Protect from light. Temperature avoid >95 °F.

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: Sulphur oxides, carbon monoxide and carbon dioxide.

Thermal decomposition: no data available

11. Toxicological information

Toxicological tests

Acute toxicity: LD50 Rat, oral: (MMA) > 5000 mg/kg
LD50 Rabbit, dermal: (MMA) > 5000 mg/kg
LC50 Rat, inhalative: (MMA) 29.8 mg/L/4h
NOAEL Rat, inhalative: (MMA) 25 ppm/2a
NOAEL Rat, oral: (MMA) 2000 ppm/2a

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.

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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: 172 mg/kg

Symptoms

Potential health effects.
In case of inhalation: Cough and shortage of breath.
In case of ingestion: Methyl methacrylate:
Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.
After contact with skin: Danger of cutaneous absorption.
After eye contact: May cause irritations.

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12. Ecological information**Ecotoxicity**

Aquatic toxicity: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Information about Triclosan:

Algae toxicity:

IC50 algae: 0,2 mg/L/72 h (OECD 201).

Daphnia toxicity:

EC50 Daphnia: 0,4 mg/L/48 h (OECD 202).

Fish toxicity:

LC50 Brachydanio rerio (zebra-fish): 0,7 mg/L/48 h.

Information about 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)

EC50 Daphnia magna: 49mg/L, 21d (OECD 202/2)

LOEL Daphnia magna: 68mg/L, 21d (OECD 202/2)

NOEL Daphnia magna: 37mg/L, 21d (OECD 202/2)

Fish toxicity:

LC50 Oncorhynchus mykiss >79 mg/L/96h (OECD 203)

Mobility in soil

no data available

Persistence and degradability

Further details: Biodegradation: 94 %/14 d (MMA, OECD 301C.)

Product is readily biodegradable.

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

Additional ecological information

Volatile organic compounds (VOC):

approx. 60 % by weight = 600 g/L

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

In case of spills of large quantities: Danger to drinking water.

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
 Remarks: Attention! IATA 3.3.3.1:
 single pack >= 30 L for passenger aircraft or
 single pack >= 100 L for cargo aircraft --> PG II



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: yes
 Segregation group: none
 Remarks: Attention! IMDG 2.3.2.3: single pack >= 30 L --> PG II

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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
 Remarks: Attention! IATA 3.3.3.1:
 single pack >= 30 L for passenger aircraft or
 single pack >= 100 L for cargo aircraft --> PG II

15. Regulatory information

National regulations - U.S. Federal Regulations

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 XO
 SOCM 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

Triclosan: TSCA Inventory: listed
 TSCA HPVC: not listed

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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

Ethylen-di(S-thioacetate): Massachusetts Haz. Substance codes: 6
 Pennsylvania Haz. Substance code: -

National regulations - Great Britain

Hazchem-Code: •3YE

16. Other information

Text for labeling: Contains 40 - 70 % Methyl methacrylate, 0.1 - 1 % N,N-bis-(2-hydroxypropyl)-p-toluidine, 0.1 - 1 % Ethylen-di(S-thioacetate), 0.25 - 1 % Triclosan. 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
 JT Baker Storage Color Code: Red (Flammable Hazard)

HEALTH	2
FLAMMABILITY	3
PHYSICAL HAZARD	0
	X

Reason of change: Changes in section 1: Address

Date of first version: 4/7/2010

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.