1. Product and company identification

Product identifier

Trade name: 636K7 - ORTHOCRYL Putty

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: pasty
Color: gray
Odor: ester-like
Classification: Flammable Solid - Category 1; Skin Irritation - Category 2; Sensitization - skin - Category 1;
Hazard symbols:

Signal word: **Danger**
Hazard statements: Flammable solid.
Causes skin irritation.
May cause an allergic skin reaction.

Precautionary statements:

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Avoid breathing vapors.
Wear protective gloves/protective clothing/eye protection/face protection.
If skin irritation or rash occurs: Get medical advice/attention.

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 are heavier than air and will travel at floor level.
In case of fire, explosive mixtures may form with air.
Heating will lead to pressure increase: Danger of bursting and explosion.
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.

After resorption of toxic quantities: CNS disorders.
see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Polymer resin solution with fillers with a polyester base in methylmethacrylate

Relevant ingredients:

CAS No.	Designation	Content	Classification
CAS 80-62-6	Methyl methacrylate	10 - 30 %	Flammable Liquid - Category 2. Skin Irritation - Category 2. Sensitization - skin - Category 1. Specific Target Organ Toxicity (Single Exposure) - Category 3.
CAS 141-32-2	n-Butyl acrylate	1 - 5 %	Flammable Liquid - Category 3. Skin Irritation - Category 2. Eye Irritation - Category 2A. Sensitization - skin - Category 1. Specific Target Organ Toxicity (Single Exposure) - Category 3.

4. First aid measures

General information:
Take off immediately all contaminated clothing.
Always seek medical assistance if symptoms develop that are possibly due to exposure through skin or eye contact or through inhalation of fumes.
Call a doctor if you feel unwell.
Never give anything by mouth to an unconscious person.
If unconscious place in recovery position and seek medical advice.

In case of inhalation:
Move victim to fresh air, provide oxygen as needed. 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: Rinse mouth immediately and drink plenty of water. 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.
Information about Methyl methacrylate:
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.

Information to physician

Monitor breathing. Treat symptomatically.
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.

5. Fire fighting measures

Flash point/flash point range:
84.2 °F (DIN 51755)

Auto-ignition temperature: No data available

Suitable extinguishing media:
Water spray jet, foam, dry chemical powder, carbon dioxide

Extinguishing media which must not be used for safety reasons:
strong water jet

Specific hazards arising from the chemical

Flammable solid. Heating will lead to pressure increase: Danger of bursting and explosion. Potentially explosive vapor/air mixtures may form.
Polymerization along with heat production.
In case of fire may be liberated: 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: Cool endangered containers with water spray and, if possible, remove from danger zone.
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 appropriate protective equipment. Avoid breathing vapors.
Avoid contact with skin and eyes.
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: Take up mechanically, placing in appropriate containers for disposal.

Additional information: Take precautionary measures against static discharges. 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.
Avoid breathing 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.
Ground/bond container and receiving equipment.
In case of fire, cool endangered containers with water.
Use explosion-proof equipment and non-sparking tools/utensils.
Avoid shock and friction.

Potentially explosive vapor/air mixtures may form.
Vapors are heavier than air and will travel at floor level.

Storage

Requirements for storerooms and containers:
Keep only in the original container at temperature not exceeding 86 °F.
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.
Protect against heat /sun rays.
Protect from light. Store containers in upright position. Explosion protection required.

Hints on joint storage: Do not store together with organic peroxides, ammonia or persulphates.
keep away from acids.
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
141-32-2	n-Butyl acrylate	USA: ACGIH: TWA	11 mg/m³; 2 ppm
		USA: NIOSH: TWA	55 mg/m³; 10 ppm

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: Use solvent-resistant protective clothing.
In case of handling larger quantities: Flame-resistant antistatic protective clothing

Protective gloves according to OSHA Standard - 29 CFR: 1910.138.
Glove material: butyl caoutchouc (butyl rubber) (0.7 mm)
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.
identification color brown.

General hygiene considerations:
Do not breathe vapors. Avoid contact with skin and eyes.
Separate storage of work clothes.
Take off immediately all contaminated clothing.
When using do not eat, drink or smoke.
Keep away from food, drink and animal feedingstuffs. Wash hands before breaks and after work.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Form: pasty Color: gray
Odor:	ester-like
Odor threshold:	No data available
pH value:	not applicable
Melting point/freezing point:	-54.4 °F
Initial boiling point and boiling range:	No data available
Flash point/flash point range:	84.2 °F (DIN 51755)
Evaporation rate:	No data available
Flammability:	Flammable solid.
Explosion limits:	LEL (Lower Explosion Limit): (Methylmethacrylat) 2.10 Vol-% UEL (Upper Explosive Limit): (Methylmethacrylat) 12.50 Vol-%
Vapor pressure:	at 68 °F: <= 40 hPa
Vapor density:	No data available
Density:	at 68 °F: 2.3 g/cm³
Solubility:	at 68 °F: soluble in acetone
Water solubility:	at 68 °F: not established
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: pasty
Explosive properties:	Product is not explosive. Potentially explosive vapor/air mixtures may form.
Ignition temperature:	(Methylmethacrylat) 806 °F
Additional information:	Relative vapor density at 68 °F (air=1): >1

10. Stability and reactivity

Reactivity: Flammable solid.

Chemical stability: Stable under recommended storage conditions.

Possibility of hazardous reactions

Vapors are heavier than air and will travel at floor level.
In case of fire, explosive mixtures may form with air.
Heating will lead to pressure increase: Danger of bursting and explosion.

Due to reducing substances, peroxides and heavy metal ions, polymerization with heat generation may occur.
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.

Conditions to avoid: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Take precautionary measures against static discharge.
Protect from: light, warmness.

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): Lack of data.

Specific target organ toxicity (repeated exposure): Lack of data.

Aspiration hazard: Lack of data.

Other information:

Following information applies to the component Methyl methacrylate:
LD50 Rat, oral: 7900 mg/kg (OECD 401)
LC50 Rat, inhalative: 7093 ppm/4h = 29,8 mg/L/4h
LD50 Rabbit, dermal: >5000 mg/kg
Irritant effect on the eye: Rabbit: Not an irritant (Draize)
Varying incidences of allergic reactions have been observed in humans. (Symptoms: Headache, eye irritations, skin problems)
In-vitro Mutagenicity:
Gene-mutations mammalian cells: inconclusive (OECD 476).
Chromosomal aberrations mammalian cells: inconclusive.
Bacterial mutagenicity: negative (Ames test, OECD 471) .
In-vivo Mutagenicity:
Chromosomal aberrations mammalian cells, rat: negative.
Micronucleus test:, Mouse: negative (OECD 474).
Teratogenicity:
Rat, inhalative: 2028 ppm, 6 - 15 d
Product did not show any carcinogenous, mutagenous or teratogenic effects in animal experiments.

Chronic toxicity:
NOAEL (oral), rat: 124.1 mg/kg bw/d.
NOAEC (inhalative), rat: 2028 mg/m³.
Target organ: nose

Symptoms: Damage of the mucous membranes in nose, throat and lungs. Degeneration of olfactory epithelia.
Estimated lethal dose: 30g

Symptoms

Information about Methyl methacrylate:
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.
In case of inhalation: 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.
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)
EC50 Selenastrum capricornutum: >100mg/L/48h
Bacterial toxicity:
EC0 Pseudomonas putida: 100 mg/L
Daphnia toxicity:
EC50 Daphnia magna (Big water flea): 69mg/L, 48h (OECD 202)
NOEC Daphnia magna (Big water flea): 37 mg/L/21d (OECD 202)
Fish toxicity:
LC50 Oncorhynchus mykiss >79 mg/L/96h (OECD 203)
NOEC Oncorhynchus mykiss >40 mg/L/96h (OECD 203)
NOEC Brachydanio rerio (zebra-fish): 9,4 mg/kg (OECD 210)

Further details: Do not allow to penetrate into soil, waterbodies or drains.

Mobility in soil

No data available

Persistence and degradability

Further details: 30,7% exceeding 28 days: Product is not readily biodegradable. (OECD 301C)
Monomer(s): degradable

Additional ecological information

Volatile organic compounds (VOC):
19 % by weight = 437 g/L

General information: Do not allow to enter into ground-water, surface water 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:	UN3175
Proper shipping name:	UN 3175, UN 3175, SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (Methyl methacrylate)
Hazard class or Division:	4.1
Packing Group:	II
Labels:	4.1
Symbols:	G
Special provisions:	47, IB6, IP2, T3, TP33
Packaging – Exceptions:	151
Packaging – Non-bulk:	212
Packaging – Bulk:	240
Quantity limitations – Passenger aircraft / rail:	15 kg
Quantity limitations – Cargo only:	50 kg
Vessel stowage – Location:	B

Sea transport (IMDG)

UN number:	UN 3175
Proper shipping name:	UN 3175, SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (Methyl methacrylate)
Class or division, Subsidary risk:	Class 4.1, Subrisk -
Packing Group:	II
EmS:	F-A, S-I
Special provisions:	216, 274
Limited quantities:	1 kg
Excepted quantities:	E2
Contaminated packaging - Instructions:	P002
Contaminated packaging - Provisions:	PP9
IBC - Instructions:	IBC06
IBC - Provisions:	B21
Tank instructions - IMO:	-
Tank instructions - UN:	T3, BK2
Tank instructions - Provisions:	TP33
Stowage and handling:	Category B.
Properties and observations:	Mixtures of non-dangerous solids (such as soil, sand, production materials etc.) and flammable liquids.
Marine pollutant:	no
Segregation group:	none

Air transport (IATA)

UN/ID number:	UN 3175
Proper shipping name:	UN 3175, SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (Methyl methacrylate)
Class or division, Subsidary risk:	Class 4.1
Packing Group:	II
Hazard label:	Flamm. solid
Excepted Quantity Code:	E2
Passenger and Cargo Aircraft: Ltd.Qty.:	Pack.Instr. Y441 - Max. Net Qty/Pkg. 5 kg
Passenger and Cargo Aircraft:	Pack.Instr. 445 - Max. Net Qty/Pkg. 15 kg
Cargo Aircraft only:	Pack.Instr. 448 - Max. Net Qty/Pkg. 50 kg
Special provisions:	A46
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

n-Butyl acrylate:

TSCA Inventory: listed
TSCA HPVC: not listed
Carcinogen Status:
  IARC Rating: Group 3
  OSHA Carcinogen: not listed
  NTP Rating: not listed
Clean Air Act:
  SOCMI Chemical: yes
Other Environmental Laws:
  SARA Title III Section 313, Toxic Release: Conc. 1.0% / Threshold Standard
NIOSH Recommendations:
  Occupational Health Guideline: 0075*

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

n-Butyl acrylate:
Delaware Air Quality Management List:
DRQ: 100
RQ State: State requirement differs from Federal
Idaho Air Pollutant List:
Title 585 -- AAC: 2.75 -- EL: 3.67 -- WEL: 55
Title 586 -
Massachusetts Haz. Substance codes: 4,5,6 F9
Minnesota Haz. Substance:
Codes: A -- Ratings: - -- Status: Title III. TRI.
New Jersey RTK Hazardous Substance:
DOT: 2348 - Sub No.: 0278 - TPQ: -
Pennsylvania Haz. Substance code: E
Washington Air Contaminant:
TWA: 10 ppm / 55 mg

National regulations - Great Britain

Hazchem-Code: 1Z

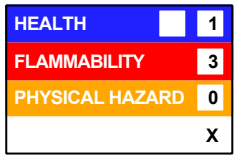
16. Other information

Text for labeling: Contains 10 - 30 % Methyl methacrylate, 1 - 5 % n-Butyl acrylate. Safety data sheet available on request.

Hazard rating systems:

NFPA Hazard Rating:
Health: 1 (Slight)
Fire: 3 (Serious)
Reactivity: 0 (Minimal)

HMIS Version III Rating:
Health: 1 (Slight)
Flammability: 3 (Serious)
Physical Hazard: 0 (Minimal)
Personal Protection: X = Consult your supervisor



Reason of change: Changes in section 1.3: Corporate headquarters
Date of first version: 10/26/1994

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.