

1. Product and company identification

Product identifier

Trade name: 636K7 - ORTHOCRYL Putty

This safety data sheet pertains to the following products:
636K7=1 = Orthocryl-Spachtel

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

Form: pasty

Color: varying

Odor: characteristic

Classification: Flammable Liquid 2. Skin Irritation 2. Sensitization - skin 1. Reproductive toxicity 2.

Hazard symbols:



Signal word:

Danger

Hazard statements: Highly flammable liquid and vapor.
Causes skin irritation.
May cause an allergic skin reaction.
Suspected of damaging the unborn child.

Precautionary statements: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Keep container tightly closed.
Avoid breathing vapors.
Wear protective gloves/protective clothing/eye protection.
If skin irritation or rash occurs: Get medical advice/attention.
In case of fire: Use dry powder, foam or water spray for extinction.
Store in a well-ventilated place. Keep cool.

Regulatory status

This material is considered hazardous by the WHMIS in Canada.

Hazards not otherwise classified

Potentially explosive mixtures may form if adequate ventilation is not provided.
Inhaling can lead to irritations of the respiratory tract and mucous membrane.
Higher doses may lead to a narcotic effect.
Special danger of slipping by leaking/spilling product.
see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterisation: Mixture of the substances listed below with non-hazardous additions:

Relevant ingredients:

CAS No.	Designation	Concentration	Classification
CAS 80-62-6	Methyl methacrylate	12.5 - < 20 %	Flammable Liquid 2. Skin Irritation 2. Sensitization - skin 1. Specific Target Organ Toxicity (Single Exposure) 3.
CAS 109-16-0	2,2'-Ethylenedioxydiethyl dimethacrylate	< 1 %	Sensitization - skin 1.
CAS 38668-48-3	1,1'-(p-Tolylimino) dipropan-2-ol	< 1 %	Acute Toxicity 2 (oral). Eye Irritation 2A. Aquatic toxicity - chronic 3.
CAS 100-42-5	Styrene	< 1 %	Flammable Liquid 3. Acute Toxicity 4 (inhalative). Skin Irritation 2. Eye Irritation 2A. Reproductive toxicity 2. Specific Target Organ Toxicity (Single Exposure) 3. Specific Target Organ Toxicity (Repeated Exposure) 1. Aspiration Toxicity 1. Aquatic toxicity - chronic 3.
CAS 123-81-9	Ethylene di(S-thioacetate)	< 1 %	Acute Toxicity 4 (oral). Acute Toxicity 4 (dermal). Acute Toxicity 4 (inhalative). Eye Irritation 2A. Sensitization - skin 1. Specific Target Organ Toxicity (Single Exposure) 3.
CAS 33007-83-9	2-ethyl-2-[(3-mercapto-1-oxopropoxy)methyl] propane-1,3-diyl bis[3-mercaptopropionate]	< 0.25 %	Acute Toxicity 4 (oral). Sensitization - skin 1. Aquatic toxicity - acute 1. Aquatic toxicity - chronic 1.

Additional information: Contains Silicon dioxide.
The maximum workplace exposure limits are, where necessary, listed in section 8.

4. First aid measures

General information:	If medical advice is needed, have product container or label at hand. First aider: Pay attention to self-protection! Take off contaminated clothing and wash it before reuse.
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. 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. In case of eye irritation consult an ophthalmologist.
After swallowing:	Rinse mouth immediately and drink plenty of water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Seek medical attention.

Most important symptoms and effects, both acute and delayed

Causes skin irritation.

May cause an allergic skin reaction.

Inhaling can lead to irritations of the respiratory tract and mucous membrane.

Higher doses may lead to a narcotic effect.

Information to physician

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range:

10 °C

Auto-ignition temperature: No data available

Suitable extinguishing media:

Water spray jet, extinguishing powder, carbon dioxide, alcohol resistant foam.

Extinguishing media which must not be used for safety reasons:

Full water jet

Specific hazards arising from the chemical

Highly flammable liquid and vapor. 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: Nitrogen oxides (NO_x), 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. Keep containers cool with water spray.

In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.

Do not allow fire water to penetrate into surface or ground water.

Fire residuals and contaminated extinguishing water must be disposed of in accordance with the regulations of the local authorities.

6. Accidental release measures

Personal precautions:

Avoid exposure. Eliminate all ignition sources if safe to do so. If possible, eliminate leakage. Provide adequate ventilation.

Wear appropriate protective equipment. Avoid breathing vapors. Avoid contact with skin and eyes. Take off contaminated clothing and wash it before reuse.

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.

In case of release, notify competent authorities. Danger of explosion!

Methods for clean-up:	Isolate leaked material using non-flammable absorption agent (e.g. sand, earth, vermiculit, diatomaceous earth) and collect it for disposal in appropriate containers in accordance with the local regulations (see section 13). Beware of reignition. Thoroughly clean surrounding area. In case of greater quantities: Collect mechanically (use only explosion-proof equipment when pumping out). Never return spills in original containers for re-use.
Additional information:	Take precautionary measures against static discharges. 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:	Obtain special instructions before use. Avoid contact during pregnancy/while nursing. Provide adequate ventilation, and local exhaust as needed. Avoid breathing vapors. Do not get in eyes, on skin, or on clothing. Wear appropriate protective equipment. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Take off contaminated clothing and wash it before reuse. Guarantee sufficient ventilation during and after use, in order to prevent vapour accumulation. When handling large quantities, supply emergency spray.
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 container tightly closed and in a well-ventilated place. Keep container dry. Keep only in original container. Protect from heat and direct sunlight. Store containers in upright position.
Hints on joint storage:	Keep away from food, drink and animal feedingstuffs. Do not store together with: Oxidizing agents, acids, bases, peroxides, radical formers.

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
100-42-5	Styrene	Canada: OEL 15 min	170 mg/m ³ ; 40 ppm
		Canada: OEL 8 hour	85 mg/m ³ ; 20 ppm
		Canada: OEL STEL	100 ppm
		Canada: OEL STEL	20 ppm
		Canada: OEL TWA	10 ppm
		Canada: OEL TWA	35 ppm
		Canada: VECD	75 ppm
		Canada: VEMP	50 mg/m ³

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: Fluororubber (Viton)
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.
Wear half-mask respirator with combination filter for organic vapors and particles.
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:

Obtain special instructions before use. Avoid contact during pregnancy/while nursing.
Avoid breathing vapors. Do not get in eyes, on skin, or on clothing. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Take off contaminated clothing and wash it before reuse. Guarantee sufficient ventilation during and after use, in order to prevent vapour accumulation.
When handling large quantities, supply emergency spray.

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 Form: pasty Color: varying
Odor:	characteristic
Odor threshold:	No data available
pH:	not applicable
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	101 °C
Flash point/flash point range:	10 °C
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 20 °C: 47 hPa
Vapor density:	No data available
Density:	at 20 °C: 2.01 g/cm ³
Water solubility:	at 20 °C: immiscible
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	No data available
Viscosity, dynamic:	at 20 °C: 38,500 mPa*s
Explosive properties:	Product is not explosive. Potentially explosive vapor/air mixtures may form.
Ignition temperature:	430 °C
Solvent content:	18.2 %
Solid content:	67.5 %

10. Stability and reactivity

Reactivity:	Highly flammable liquid and vapor. Vapors may form explosive mixtures with air.
Chemical stability:	Stable under recommended storage conditions.
Possibility of hazardous reactions:	Heating will lead to pressure increase: Danger of bursting and explosion. Polymerization along with heat production. Reactions with strong oxidizing agents, strong alkalis, strong acids, peroxides and radical formers.
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, warmth.
Incompatible materials:	Oxidising agent, acids, alkalis, peroxides, radical former

Hazardous decomposition products:

Nitrogen oxides (NO_x), carbon monoxide and carbon dioxide

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 (calculated): > 5,000 mg/kg

Acute toxicity (dermal): Based on available data, the classification criteria are not met.

Acute toxicity (inhalative): Based on available data, the classification criteria are not met.

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: Reproductive toxicity 2 = Suspected of damaging the unborn child.

Effects on or via lactation: Lack of data.

Specific target organ toxicity (single exposure): Based on available data, the classification criteria are not met.

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 80-62-6):

LD50 Rat, oral: approx. 7,900 mg/kg

LD50 Rabbit, dermal: > 5,000 mg/kg (OECD 402)

LC50 Rat, inhalative: 29.8 mg/L/4h

Information about 2,2'-Ethylenedioxydiethyl dimethacrylate (CAS 109-16-0):

LD50 Rat, oral: > 2,000 mg/kg

LD50 Mouse, dermal: > 2,000 mg/kg

Information about 1,1'-(p-Tolylimino)dipropyl-2-ol (CAS 38668-48-3):

LD50 Rat, oral: 25 - 200 mg/kg

LD50 Rabbit, dermal: > 2,000 mg/kg

Information about Styrene (CAS 100-42-5):

LD50 Rat, oral: > 2,000 mg/kg

LD50 Rat, dermal: > 2,000 mg/kg

LC50 Rat, inhalative: 11.8 mg/L/4h

Symptoms

Shortage of breath, headache, drowsiness, dizziness, cough, nausea

12. Ecological information

Ecotoxicity

Aquatic toxicity:

Information about Methyl methacrylate (CAS 80-62-6):

Fish toxicity:

LC50 Oncorhynchus mykiss: > 100 mg/L/96h

NOEC Danio rerio (zebrafish): 9.4 mg/L/35d (OECD 210)

Daphnia toxicity:

EC50 Daphnia magna (Big water flea): 69 mg/L/48h

NOEC Daphnia magna (Big water flea): 37 mg/L/21d (OECD 211)

Algae toxicity:

EC50 Pseudokirchneriella subcapitata (green algae), growth rate: >110 mg/L/72h (OECD 201)

NOEC Pseudokirchneriella subcapitata (green algae), growth rate: 110 mg/L/72h

Information about 2-ethyl-2-[(3-mercapto-1-oxopropoxy)methyl]propane-1,3-diyl

bis[3-mercaptopropionate] (CAS 33007-83-9):

Fish toxicity:

LC50 Oncorhynchus mykiss: 0.153 mg/L/96h

Daphnia toxicity:

EC50 Daphnia magna (Big water flea): 0.71 mg/L/48h

Information about Styrene (CAS 100-42-5):

Fish toxicity:

LC50 Pimephales promelas (fathead minnow): 4.02 mg/L/96h

Daphnia toxicity:

EC50 Daphnia magna (Big water flea): 4.7 mg/L/48h

Algae toxicity:

EC50 Selenastrum capricornutum (green algae), growth rate: 4.9 mg/L/72h

Mobility in soil

No data available

Persistence and degradability

Further details:

No data available

Additional ecological information

Volatile organic compounds (VOC):

18.09 % by weight

General information:

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

13. Disposal considerations

Product

Recommendation:

Dispose of waste according to applicable legislation. Do not empty into drains. Do not dispose of with household waste.

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.

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:

II

Explosive limit and limited quantity index:

5 L

Passenger carrying road or rail index:

5 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

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

15. Regulatory information

National regulations - Canada

Methyl methacrylate: DSL: listed
 Silicon dioxide: DSL: listed
 2,2'-Ethylenedioxydiethyl dimethacrylate: DSL: listed
 1,1'-(p-Tolylimino)dipropen-2-ol: DSL: listed
 Styrene: DSL: listed
 Ethylene di(S-thioacetate): DSL: listed
 2-ethyl-2-[(3-mercapto-1-oxopropoxy)methyl]propane-1,3-diyl bis[3-mercaptopropionate]: DSL: listed

16. Other information

Text for labeling: Contains 12.5 - < 20 % Methyl methacrylate, < 1 % 2,2'-Ethylenedioxydiethyl dimethacrylate, < 1 % 1,1'-(p-Tolylimino)dipropen-2-ol, < 1 % Styrene, < 1 % Ethylene di(S-thioacetate), < 0.25 % 2-ethyl-2-[(3-mercapto-1-oxopropoxy)methyl]propane-1,3-diyl bis[3-mercaptopropionate].

Hazard rating systems:



NFPA Hazard Rating:

Health: 2 (Moderate)
 Fire: 4 (Severe)
 Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 2 (Moderate) - Chronic effects
 Flammability: 4 (Severe)
 Physical Hazard: 0 (Minimal)
 Personal Protection: X = Consult your supervisor

HEALTH	*	2
FLAMMABILITY		4
PHYSICAL HAZARD		0
X		

Classification procedure: Physical hazards: on basis of test data
 Health hazards, environmental 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 - acute: Hazardous to the aquatic environment - acute
 Aquatic toxicity - chronic: Hazardous to the aquatic environment - chronic
 AS/NZS: Australian Standards/New Zealand Standards
 Aspiration Toxicity: Aspiration toxicity
 ATEMix: Acute Toxicity Estimate of mixture
 CAS: Chemical Abstracts Service
 CFR: Code of Federal Regulations
 CLP: Classification, Labelling and Packaging
 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 Irritation: Eye irritation
 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
 NOEC: No Observed Effect Concentration
 OEL: Occupational Exposure Limit Value
 OSHA: Occupational Safety and Health Administration
 PBT: Persistent, bioaccumulative and toxic
 PNEC: Predicted no-effect concentration
 Reproductive toxicity: Reproductive toxicity
 RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
 Sensitization - skin: Skin sensitisation
 Skin Irritation: Skin irritation
 STOT RE: Specific target organ toxicity - repeated exposure
 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 2: Classification, labelling
 Changes in section 3: Composition/information on ingredients
 Changes in section 8: Occupational exposure limit values
 Changes in section 15: Regulatory information
 General revision

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.