

1. Product and company identification

Product identifier

Trade name: 636K18 - Sealing Resin Adhesive Gel

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

General use: Adhesive, 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

Department 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, viscous

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.
- Avoid breathing vapors.
- Use only outdoors or in a well-ventilated area.
- Wear protective gloves/protective clothing/eye protection/face 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).

Hazards not otherwise classified

Vapors form potentially explosive mixtures with air, which are heavier than air. Air-Vapor mixture may travel great distances at floor level and lead to backflash when exposed to an ignition source.

see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Acrylic resin, contains Methyl methacrylate (MMA)

Relevant ingredients:

CAS No.	Designation	Concentration	Classification
CAS 80-62-6	Methyl methacrylate	50 - 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	< 1 %	Acute Toxicity - oral - Category 3. Eye Damage - Category 1. Aquatic toxicity - chronic - Category 3.

4. First aid measures

General information:

- Take off immediately all contaminated clothing.
- 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:

- Immediately clean with water and soap and, if available, apply a generous amount of polyethylene glycol 400.
- 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

May cause respiratory irritation. Causes skin irritation. May cause an allergic skin reaction. The following symptoms may occur: headache, shortage of breath, drowsiness, cough, dizziness, asthma, Sweating.

After resorption of toxic quantities: cardiovascular disorders, modification of hemogram, Blood pressure drop, Gastric and intestinal problems.

Information to physician

Treat symptomatically.

Monitor breathing. 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.

In case of swallowing, gastric irrigation with activated carbon as an additive.

Estimated lethal dose: 30g

5. Fire fighting measures

Flash point/flash point range:

50 °F

Auto-ignition temperature: not self-igniting

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

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 (NOx), acetic acid, carbon monoxide and carbon dioxide. Toxic gases may form.

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. You have to dispose of contaminated extinguishing water according to the regulations of the authorities.

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.

Avoid contact with the substance. Provide adequate ventilation.

Avoid breathing vapors.

Keep unprotected people away. Wear appropriate protective equipment.

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: Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents) and place in closed containers for disposal.

Additional information: Use only non-sparking tools. Take precautionary measures against static discharges.

7. Handling and storage

Handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed.
Do not breathe vapor/aerosol. Avoid contact with skin and eyes.
Avoid the formation of aerosol. Wear appropriate protective equipment.

Precautions against fire and explosion:
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Take precautionary measures against static discharges.
Ground/bond container and receiving equipment.
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 in a cool, well-ventilated place. Keep container dry.
Container should not be closed gas-tight. Keep only in the original container.
Protect against heat /sun rays.
Protect from light.
Provide room air exhaust at ground level.
Store containers in upright position. Explosion protection required.

Hints on joint storage: Do not store together with combustible materials or highly flammable solids.
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/m ³ ; 100 ppm
		USA: ACGIH: TWA	205 mg/m ³ ; 50 ppm
		USA: IDLH: TWA	1,000 ppm
		USA: NIOSH: TWA	410 mg/m ³ ; 100 ppm
		USA: OSHA: TWA	410 mg/m ³ ; 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:	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). Breakthrough time: >480 min. Unsuitable materials: natural rubber (Caoutchouc), latex. 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 combination filter type A/P according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.
General hygiene considerations:	Do not breathe vapor/aerosol. Avoid contact with skin and eyes. When using do not eat, drink or smoke. Keep away from food, drink and animal feedingstuffs. Take off immediately all contaminated clothing. Separate storage of work clothes. Wash hands before breaks and after work.

Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Form: liquid, viscous Color: colorless
Odor:	ester-like
Odor threshold:	No data available
pH:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	213.8 °F
Flash point/flash point range:	50 °F
Evaporation rate:	No data available
Flammability:	Highly flammable liquid and vapor.
Explosion limits:	LEL (Lower Explosion Limit): 2.10 Vol-% UEL (Upper Explosive Limit): (Methyl methacrylate) 12.50 Vol-%
Vapor pressure:	at 68 °F: 47 hPa
Vapor density:	No data available
Density:	at 68 °F: 1.06 g/cm ³
Solubility:	alcohol
Water solubility:	at 68 °F: 16 g/L
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	not self-igniting
Thermal decomposition:	No data available

Explosive properties: Product is not explosive. Potentially explosive vapor/air mixtures may form.

Ignition temperature: 806 °F

Solid content: 27.1 %

10. Stability and reactivity

Reactivity: Highly flammable liquid and vapor.

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.
- Polymerization along with heat production.

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.

Incompatible materials: Watch for exothermic reactions with peroxides.
Reacts with acids, Radical formers.
Do not store together with organic peroxides, ammonia or persulphates.

Hazardous decomposition products:

- In case of fire may be liberated: nitrogen oxides (NO_x), acetic acid, carbon monoxide and carbon dioxide. Toxic gases may form.

Thermal decomposition: No data available

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:

Following information applies to the component Methyl methacrylate:

LD50 Rat, oral: 7872 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: 2,028 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

Can damage your health.

The following symptoms may occur: Headache, Drowsiness, dizziness, Nausea, Asthma, Loss of appetite, Modification of hemogram, Blood pressure drop, Gastric and intestinal problems, dizziness, Sweating, Danger of respiratory disorders.

After resorption of toxic quantities: cardiovascular disorders, modification of hemogram, Blood pressure drop, Gastric and intestinal problems.

In case of inhalation: Mucous membrane irritation, Cough and shortage of breath.

In case of ingestion: Methyl methacrylate:

Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.

After eye contact: causes tears

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): 69 mg/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 Danio rerio (zebrafish): 9,4 mg/kg (OECD 210)

Mobility in soil

No data available

Persistence and degradability

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

Product is readily biodegradable.

Additional ecological information

Volatile organic compounds (VOC):

89 % by weight / 945.6 g/L

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.

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 1133

UN proper shipping name

ADR/RID, IMDG, IATA-DGR:

UN 1133, ADHESIVES

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

USA: Department of Transportation (DOT)

Identification number: UN1133
Proper shipping name: UN 1133, ADHESIVES
Hazard class or Division: 3
Packing Group: II
Labels: 3
Special Provisions: 149, B52, IB2, T4, TP1, TP8
Packaging – Exceptions: 150
Packaging – Non-bulk: 173
Packaging – Bulk: 242
Quantity limitations – Passenger aircraft / rail: 5 L
Quantity limitations – Cargo only: 60 L
Vessel stowage – Location: B
Vessel stowage – Other:



Sea transport (IMDG)

UN number: UN 1133
Proper shipping name: UN 1133, ADHESIVES
Class or division, Subsidiary risk: Class 3, Subrisk -
Packing Group: II
EmS: F-E, S-D
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: Adhesives are solutions of gums, resins, etc., usually volatile due to the solvents. Miscibility with water depends upon their composition.
Marine pollutant: no
Segregation group: none

Air transport (IATA)

UN/ID number: UN 1133
Proper shipping name: UN 1133, ADHESIVES
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 - U.S. Federal Regulations

Methyl methacrylate: TSCA Inventory: listed
Carcinogen Status:
IARC Rating: Group 3
OSHA Carcinogen: not listed
NTP Rating: not listed
Clean Air Act:
CAA Hazardous Air Pollutants: yes
CAA SOCMII Chemical: yes
Clean Water Act:
CWA 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 Inventory: 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 - Canada

Methyl methacrylate: DSL: listed
N,N-bis-(2-hydroxypropyl)-p-toluidine: DSL: listed

National regulations - Great Britain

Hazchem-Code: •3YE

16. Other information

Text for labeling:

Contains 50 - 100 % Methyl methacrylate, < 1 % N,N-bis-(2-hydroxypropyl)-p-toluidine.
Contains Methyl methacrylate.

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

HEALTH	2
FLAMMABILITY	3
PHYSICAL HAZARD	0
	X

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 - chronic: Hazardous to the aquatic environment - chronic
 AS/NZS: Australian Standards/New Zealand Standards
 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
 EmS: Emergency Response Procedures for Ships Carrying Dangerous Goods
 EN: European Standard
 EQ: Excepted quantities
 Eye Damage: Eye damage
 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
 LD50: Lethal dose 50%
 LEL: Lower Explosion Limit
 MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
 OEL: Occupational Exposure Limit Value
 OSHA: Occupational Safety and Health Administration
 PBT: Persistent, bioaccumulative and toxic
 PNEC: Predicted no-effect concentration
 RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
 Sensitization - skin: Skin sensitisation
 Skin Irritation: Skin irritation
 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

Reason of change: Changes in section 8: Occupational exposure limit values

Date of first version: 10/27/1994

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.