

## 1. Product and company identification

### Product identifier

Trade name: 636K14 - Loctite 601

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

General use: Anaerobic adhesive, Screw Locking Agent,  
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](http://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](mailto: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**

## 2. Hazards identification

### Emergency overview

Appearance: Physical state at 68 °F and 101.3 kPa: liquid

Color: green

Odor: characteristic

Classification: Skin Irritation - Category 2; Eye Irritation - Category 2A; Sensitization - skin - Category 1; Specific Target Organ Toxicity (Single Exposure) - Category 3;  
Specific Target Organ Toxicity (Repeated Exposure) - Category 2;  
Aquatic toxicity - chronic - Category 3;

Hazard symbols:



Signal word:

**Warning**

Hazard statements:

- Causes skin irritation.
- May cause an allergic skin reaction.
- Causes serious eye irritation.
- May cause respiratory irritation.
- May cause damage to organs through prolonged or repeated exposure.
- Harmful to aquatic life with long lasting effects.

Precautionary statements:

- Do not breathe vapors.
- Use only outdoors or in a well-ventilated area.
- Wear protective gloves/protective clothing/eye protection.
- Get medical attention if you feel unwell.
- If skin irritation occurs: Get medical advice/attention.
- Wash contaminated clothing before reuse.
- Store in a well-ventilated place. Keep container tightly closed.
- Dispose of contents/container to hazardous or special waste collection point.

**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**

Special danger of slipping by leaking/spilling product.  
see section 11: Toxicological information

**3. Composition / Information on ingredients**

Chemical characterization: Anaerobic adhesive with polyethylene glycol dimethacrylate base.

### Relevant ingredients:

CAS No.	Designation	Content	Classification
CAS 109-16-0	2,2'-Ethylenedioxydiethyl dimethacrylate	50 - 100 %	Sensitization - skin - Category 1.
CAS 868-77-9	2-Hydroxyethyl methacrylate	10 - 20 %	Skin Irritation - Category 2. Eye Irritation - Category 2A. Sensitization - skin - Category 1.
CAS 63393-89-5	Coumarone-Indene Resin	< 10 %	Eye Irritation - Category 2A.
CAS 80-15-9	Cumene hydroperoxide	< 2.5 %	Organic Peroxide - Category E. Acute Toxicity - oral - Category 4. Acute Toxicity - dermal - Category 4. Acute Toxicity - inhalative - Category 3. Skin Corrosion - Category 1B. Specific Target Organ Toxicity (Repeated Exposure) - Category 2. Aquatic toxicity - chronic - Category 2.
CAS 613-48-9	N,N-diethyl-p-toluidine	< 1 %	Acute Toxicity - oral - Category 3. Acute Toxicity - dermal - Category 3. Acute Toxicity - inhalative - Category 3. Specific Target Organ Toxicity (Repeated Exposure) - Category 2. Aquatic toxicity - chronic - Category 3.
CAS 609-72-3	Dimethyltoluidine	< 1 %	Acute Toxicity - oral - Category 3. Acute Toxicity - dermal - Category 3. Acute Toxicity - inhalative - Category 3. Specific Target Organ Toxicity (Repeated Exposure) - Category 2. Aquatic toxicity - chronic - Category 3.
CAS 79-41-4	Methacrylic acid	< 1 %	Acute Toxicity - oral - Category 4. Acute Toxicity - dermal - Category 3. Acute Toxicity - inhalative - Category 4. Skin Corrosion - Category 1A.

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

## 4. First aid measures

General information:	Take off immediately all contaminated clothing. If medical advice is needed, have product container or label at hand.
In case of inhalation:	Move victim to fresh air. Seek medical attention if problems persist.
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. Remove contact lenses, if present and easy to do. Continue rinsing. Consult doctor afterwards.

After swallowing: Rinse mouth immediately and drink plenty of water.  
Do not induce vomiting. Consult physician.

### Most important symptoms/effects, acute and delayed

May cause respiratory irritation.  
Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation.

### Information to physician

Treat symptomatically.

## 5. Fire fighting measures

Flash point/flash point range:

> 212 °F (COC)

Auto-ignition temperature: No data available

Suitable extinguishing media:

Dry chemical powder, foam, Carbon dioxide

### Specific hazards arising from the chemical

Emits toxic fumes under fire conditions.  
In case of fire may be liberated: Nitrogen oxides (NOx), carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters:

Wear self-contained positive pressure breathing apparatus and full firefighting protective clothing.

## 6. Accidental release measures

Personal precautions: Provide adequate ventilation. Avoid contact with skin and eyes. Do not breathe vapors.  
Wear appropriate protective equipment. Take off immediately all contaminated clothing and wash it before reuse. Keep unprotected people away.

Environmental precautions:

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

Methods for clean-up:

Smaller amounts: Collect spilled material using paper towels and dispose.  
Large amounts: Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents) and place in closed containers for disposal. Special waste.  
Clean contaminated area with soap and water. Provide adequate ventilation.

Additional information:

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. Do not breathe vapors.  
Avoid contact with skin, eyes, and clothing. Wear appropriate protective equipment. Take off immediately all contaminated clothing and wash it before reuse.  
Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling.  
Have eye wash bottle or eye rinse ready at work place.

Specific use(s)

Anaerobic adhesive, Screw Locking Agent for orthopedic procedures

### Storage

Requirements for storerooms and containers:

Keep only in the original container.

Do not return unused portions of product to original container.

Hints on joint storage:

Do not store together with Strong oxidizing agents.

## 8. Exposure controls / personal protection

### Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
98-82-8	Cumene	USA: ACGIH: TWA	246 mg/m <sup>3</sup> ; 50 ppm
		USA: NIOSH: TWA	245 mg/m <sup>3</sup> ; 50 ppm
		USA: OSHA: TWA	245 mg/m <sup>3</sup> ; 50 ppm
79-41-4	Methacrylic acid	USA: ACGIH: TWA	70 mg/m <sup>3</sup> ; 20 ppm
		USA: NIOSH: TWA	70 mg/m <sup>3</sup> ; 20 ppm

### Engineering controls

Provide local exhaust as close as possible to point of adhesion.

To minimize skin contact, Loctite applicators are recommended. Do not breathe vapors.

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: Wear suitable protective clothing.

Protective gloves according to OSHA Standard - 29 CFR: 1910.138.

Glove material: Nitrile rubber- - Layer thickness:  $\geq 0,4$  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:

Do not breathe vapors. Keep away from food and drinks. Do not eat, drink or smoke when using this product.

Avoid contact with skin, eyes, and clothing. Take off immediately all contaminated clothing and wash it before reuse.

Wash hands before breaks and after work. Follow up by applying skin cream.

Have eye wash bottle or eye rinse ready at work place.

### Environmental exposure controls

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

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

Appearance:	Physical state at 68 °F and 101.3 kPa: liquid Color: green
Odor:	characteristic
Odor threshold:	No data available
pH value:	no data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flash point/flash point range:	> 212 °F (COC)
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	No data available
Vapor pressure:	No data available
Vapor density:	No data available
Density:	at 77 °F: 1.098 g/mL
Solubility:	in CHCl <sub>3</sub> ≥ 900 g/L, in acetone miscible. at 68 °F: in organic solvents ≥ 900 g/L
Water solubility:	immiscible
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	No data available
Ignition temperature:	> 572 °F
Additional information:	Possible separation of some components at < -10°C, but no hardening. Boiling point cannot be determined since strong heating will lead to polymerization.

## 10. Stability and reactivity

Reactivity:	Refer to subsection "Possibility of hazardous reactions".
Chemical stability:	Stable under recommended storage conditions.
Possibility of hazardous reactions	Reacts with strong oxidizing agents.
Conditions to avoid:	Keep away from heat.
Incompatible materials:	Strong oxidizing agents.
Hazardous decomposition products:	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: > 2000 mg/kg

Acute toxicity (dermal): Based on available data, the classification criteria are not met.  
ATEmix calculated: > 2000 mg/kg

Acute toxicity (inhalative): Based on available data, the classification criteria are not met.  
ATEmix calculated (Dusts/mist): > 5 mg/L

Skin corrosion/irritation: Skin Irritation - Category 2 = Causes skin irritation.

Serious eye damage/irritation: Eye Irritation - Category 2A = Causes serious eye irritation.

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: Based on available data, the classification criteria are not met.

Information about 2,2'-Ethylenedioxydiethyl dimethacrylate:  
Specific symptoms in animal studies, Rat, oral: NOAEL P, F1  $\geq$  1,000 mg/kg/d (OECD 422, read across)

Information about 2-Hydroxyethyl methacrylate:  
Specific symptoms in animal studies, Rat, oral: NOAEL P,F1  $\geq$  1,000 mg/kg/d (OECD 422, read across)

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. Target organ: respiratory system

Specific target organ toxicity (repeated exposure): Specific Target Organ Toxicity (Repeated Exposure) -  
Category 2 = May cause damage to organs through prolonged or repeated exposure.

Information about 2,2'-Ethylenedioxydiethyl dimethacrylate:  
Specific symptoms in animal studies, Rat, oral: NOAEL = 1,000 mg/kg/d (OECD 422, read across)

Information about 2-Hydroxyethyl methacrylate:  
Specific symptoms in animal studies, Rat, oral: NOAEL = 100 mg/kg/d (OECD 422, read across)

Aspiration hazard: Lack of data.

Other information: Information about 2,2'-Ethylenedioxydiethyl dimethacrylate

Acute toxicity:

LD50 Rat, oral 10,837 mg/kg

LD50 Mouse, dermal > 2,000 mg/kg

Information about 2-Hydroxyethyl methacrylate

Acute toxicity:

LD50 Rat, oral > 5,000 mg/kg

LD50 Rabbit, dermal > 5,000 mg/kg

Information about Coumarone-Indene Resin

Acute toxicity:

LD50 Rat, oral > 16,000 mg/kg

Information about Cumene hydroperoxide:

Acute toxicity:

LD50 Rat, oral 550 mg/kg

LD50, dermal 1200 - 1520 mg/kg

Information about Methacrylic acid:

LD50 Rat, oral > 1320 mg/kg (OECD 401, read across)

LD50 dermal 500 mg/kg (ATE)

## Symptoms

In case of inhalation:

Irritant. cough, shortness of breath, shortage of breath, cramp feeling in breast.

In case of ingestion: Irritant

After contact with skin: skin rash, urticaria

After eye contact: irritation, redness

## 12. Ecological information

### Ecotoxicity

**Aquatic toxicity:**

Harmful to aquatic life with long lasting effects.

Cumene hydroperoxide:

Algae toxicity: *Pseudokirchneriella subcapitata* (green algae): ErC 3.1 mg/L/72h, OECD 201, read across

Daphnia toxicity: *Daphnia magna* (Big water flea) EC50: 18 mg/L/48h, OECD 202, read across

Fish toxicity: *Oncorhynchus mykiss* LC50: 3.9 mg/L/96h, OECD 203, read across

Bacterial toxicity: EC10: 70 mg/L/30min

2-Hydroxyethyl methacrylate

Algae toxicity: *Pseudokirchneriella subcapitata* (green algae): EC50 836 mg/L/72h; NOEC 400 mg/L/72h, OECD 201, read across

Daphnia toxicity: *Daphnia magna* (Big water flea) EC50: 380 mg/L/48h OECD 202, read across; NOEC 24.1 mg/L/21d, OECD 211, read across

Fish toxicity: *Oryzias latipes* LC50: > 100 mg/L/96h, OECD 203, read across

2,2'-Ethylenedioxydiethyl dimethacrylate

Algae toxicity: *Pseudokirchneriella subcapitata* (green algae): EC50 > 100 mg/L/72h; NOEC 18.6 mg/L/72h, OECD 201, read across

Daphnia toxicity: *Daphnia magna* (Big water flea) NOEC: 32 mg/L/21d, OECD 211, read across

Fish toxicity: *Brachydanio rerio* (zebra-fish) LC50: 16.4 mg/L/96h, OECD 203, read across

Methacrylic acid

Algae toxicity: *Pseudokirchneriella subcapitata* (green algae): EC50 > 45 mg/L/72h; NOEC 8.2 mg/L/72h, OECD 201, read across

Daphnia toxicity: *Daphnia magna* (Big water flea) EC50: > 130 mg/L/48h, EPA OTS 797.1300, read across

Fish toxicity: *Oncorhynchus mykiss* LC50: 85 mg/L/96h, EPA OTS 797.1400, read across

Bacterial toxicity: EC10: 100 mg/L/17h

### Mobility in soil

No data available

### Persistence and degradability

**Further details:**

2-Hydroxyethyl methacrylate: easily bio-degradable, Degradation aerobic: 92 - 100 %, OECD 301 C, read across

Cumene hydroperoxide: Degradation: 0 %, OECD 301 B, read across

2,2'-Ethylenedioxydiethyl dimethacrylate: easily bio-degradable, Degradation aerobic: 85 % OECD 301 B, read across

Methacrylic acid: easily bio-degradable, Degradation aerobic: 100 % OECD 302 B, read across

### Additional ecological information

**Volatile organic compounds (VOC):**

&lt;3 % 32.94 g/L

**General information:**

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

### 13. Disposal considerations

#### Product

Recommendation: Special waste. Dispose of waste according to applicable legislation.

#### 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)

Proper shipping name: Not restricted

#### Sea transport (IMDG)

Proper shipping name: Not restricted

Marine pollutant: no

#### Air transport (IATA)

Proper shipping name: Not restricted

#### Further information

No dangerous good in sense of these transport regulations.

### 15. Regulatory information

#### National regulations - U.S. Federal Regulations

2,2'-Ethylenedioxydiethyl dimethacrylate:	<p>TSCA Inventory: listed</p> <p>TSCA HPVC: not listed</p> <p>TSCA 8(b) inventory: listed</p>
2-Hydroxyethyl methacrylate:	<p>TSCA Inventory: listed</p> <p>TSCA HPVC: not listed</p>
Cumene hydroperoxide:	<p>TSCA Inventory: listed</p> <p>TSCA HPVC: not listed</p> <p>Clean Air Act:</p> <p>SOCMI Chemical: yes</p> <p>Other Environmental Laws:</p> <p>CERCLA: RQ 10 lbs.</p> <p>RCRA Hazardous Wastes: Code U096</p> <p>SARA Title III Section 313, Toxic Release: Conc. 1.0% / Threshold Standard</p> <p>OSHA Process Safety Management: Threshold 5000 lbs.</p>
N,N-diethyl-p-toluidine:	TSCA: listed
Dimethyltoluidine:	TSCA: listed
Cumene:	<p>TSCA Inventory: listed</p> <p>TSCA HPVC: not listed</p> <p>Clean Air Act:</p> <p>Hazardous Air Pollutants: Code XOY</p> <p>SOCMI Chemical: yes</p> <p>Other Environmental Laws:</p> <p>CERCLA: RQ 5000 lbs.</p> <p>RCRA Hazardous Wastes: Code U055</p> <p>SARA Title III Section 313, Toxic Release: Conc. 1.0% / Threshold Standard</p> <p>NIOSH Recommendations:</p> <p>Occupational Health Guideline: 0159*</p>
Methacrylic acid:	<p>TSCA: listed</p> <p>Clean Air Act:</p> <p>SOCMI Chemical: yes</p> <p>NIOSH Recommendations:</p> <p>Occupational Health Guideline: 0386*</p>

### National regulations - U.S. State Regulations

Cumene hydroperoxide: California Proposition 65 code: -  
 Delaware Air Quality Management List:  
     DRQ: 10 - RQ State: Federal Regulations Apply  
 Massachusetts Haz. Substance codes: 5,6 F8 F9  
 New Jersey Extraordinarily Hazardous Substances:  
     NJ Threshold: 2500 - NJ Group: I - NJ Table: I Part D - NJ Basis: NFPA 325  
 New Jersey RTK Hazardous Substance:  
     DOT: 2116 - Sub No.: 0543 - TPQ: -  
 New York List of Hazardous Substances:  
     RQ-Air: 10 - RQ-Land: 10 - Note: No Note Associated with this chemical.  
 Pennsylvania Haz. Substance code: E

Cumene: California Proposition 65 code: -  
 Delaware Air Quality Management List:  
     DRQ: 5000 - RQ State: Federal Regulations Apply  
 Idaho Air Pollutant List:  
     Title 585: AAC: 12.25 - EL: 16.3 - OEL: 245 - Title 586: -  
 Main Hazardous Air Pollutants:  
     Me 2005: HAP - Hap Rpt: 2000  
 Massachusetts Haz. Substance codes: 2,4,5 F8 F9  
 Minnesota Haz. Substance:  
     Codes: AO - Ratings: - - Status: Air Pollutant Title III. TRI.  
 New Jersey RTK Hazardous Substance:  
     DOT: 1928 - Sub No.: 0542 - TPQ: -  
 New York List of Hazardous Substances:  
     RQ-Air: 5000 - RQ-Land: 1 - Note: No Note Associated with this chemical.  
 Pennsylvania Haz. Substance code: E  
 Washington Air Contaminant:  
     TWA: 50 ppm - 245 mg  
     Protective measures should be taken to prevent or reduce skin absorption.  
 California Proposition 65: cancer  
 Rhode Island HSL: listed

Methacrylic acid: Idaho Air Pollutant List:  
     Title 585 -- AAC: 3.5 -- EL: 4.67 -- WEL: 70 - Title 586 -  
 Massachusetts Haz. Substance codes: 4,5,6  
 Minnesota Haz. Substance: Codes: A -- Ratings: -  
 Pennsylvania Haz. Substance code: -  
 Washington Air Contaminant:  
     TWA: 20 ppm - 70 mg  
     Skin: Protective measures should be taken to prevent or reduce skin absorption.

### National regulations - Great Britain

Hazchem-Code: -

## 16. Other information

Text for labeling: Contains 50 - 100 % 2,2'-Ethylenedioxydiethyl dimethacrylate, 10 - 20 % 2-Hydroxyethyl methacrylate, < 10 % Coumarone-Indene Resin, < 2.5 % Cumene hydroperoxide, < 1 % N,N-diethyl-p-toluidine, < 1 % Dimethyltoluidine, < 1 % Methacrylic acid. Safety data sheet available on request.

Hazard rating systems:



NFPA Hazard Rating:

Health: 2 (Moderate)

Fire: 1 (Slight)

Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 2 (Moderate) - Chronic effects

Flammability: 1 (Slight)

Physical Hazard: 0 (Minimal)

Personal Protection: X = Consult your supervisor

HEALTH	*	2
FLAMMABILITY		1
PHYSICAL HAZARD		0
		X

Reason of change:

Changes in section 1.3: Corporate headquarters

Date of first version:

6/23/2017

### 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.