

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

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

2. Hazards identification

Emergency overview

Appearance: Form: 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;

Hazard symbols:



Signal word:

Warning

Hazard statements:

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

Precautionary statements:

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 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

see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Anaerobic adhesive with polyethylene glycol dimethacrylate base.

Hazardous ingredients:

CAS No.	Designation	Content	Classification
CAS 868-77-9	2-Hydroxyethyl methacrylate	10 - 20 %	Skin Irritation - Category 2. Eye Irritation - Category 2A. Sensitization - skin - Category 1.
CAS 613-48-9	Diethyltoluidine	0.9 - 3 %	Acute Toxicity - inhalative - Category 4. Skin Irritation - Category 2. Eye Irritation - Category 2A. Specific Target Organ Toxicity (Repeated Exposure) - Category 2.
CAS 80-15-9	Cumene hydroperoxide	1 - 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 609-72-3	Dimethyltoluidine	0.1 - 0.9 %	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 98-82-8	Cumene	0.1 - 0.5 %	Flammable Liquid - Category 3. Specific Target Organ Toxicity (Single Exposure) - Category 3. Aspiration Toxicity - Category 1. Aquatic toxicity - chronic - Category 2.

4. First aid measures

General information:	Take off immediately all contaminated clothing. When seeking medical attention bring along safety data sheet.
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. 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. 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

In case of inhalation:

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

After contact with skin: skin rash, urticaria, redness, Ignition

May cause sensitisation by skin contact.

After eye contact: Irritant, conjunctivitis

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:

Carbon dioxide, dry chemical powder, foam

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 breathing apparatus. Wear gloves and safety glasses.

6. Accidental release measures

Personal precautions:

Avoid contact with skin and eyes.

Do not breathe vapors.

Wear suitable protective clothing.

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.

7. Handling and storage

Handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed.

Keep your workplace clean. Avoid contact with skin and eyes.

Use automatic applicators. Do not use product as aerosol.

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: Use containers of PE, PP only.
Further details: storage temperature: 8°C - 21°C.
Relative air humidity 40-70%.

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 ³ ; 50 ppm
		USA: NIOSH: TWA	245 mg/m ³ ; 50 ppm
		USA: OSHA: TWA	245 mg/m ³ ; 50 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:
When using do not eat, drink or smoke. Keep away from food and drinks.
Avoid contact with skin and eyes. Wash hands before breaks and after work. Follow up by applying skin cream.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance: Form: liquid
Color: green

Odor: characteristic

Odor threshold: no data available

pH value: at 71.6 °F: Acetone-water-extract 3 - 6

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

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Explosion limits:	no data available
Vapor pressure:	no data available
Vapor density:	no data available
Density:	at 77 °F: 1.098 g/mL (DIN 51757)
Solubility:	in CHCl ₃ >= 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:	> 300°C
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 10.3
Chemical stability:	Product is stable under normal storage conditions.
Possibility of hazardous reactions	In case of a lack of air and/or the existence of metal, polymerization may occur. Product is sufficiently stabilized to ensure that, in normal use, premature polymerization does not occur.
Conditions to avoid:	Keep away from heat.
Incompatible materials:	Peroxides, strong reducing agents. Reacts with strong oxidizing agents.
Hazardous decomposition products:	In case of fire may be liberated: Nitrogen oxides (NO _x), carbon monoxide and carbon dioxide.
Thermal decomposition:	> 300°C

11. Toxicological information

Toxicological tests

Acute toxicity:	LD50 Cumene hydroperoxide Rat, oral: 550 mg/kg
	LD50 Cumene hydroperoxide Rat, dermal: 500 mg/kg

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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: 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: 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:	May cause sensitisation by skin contact.
	Contains Cumene (CAS: 98-82-8): skin resorptive

Symptoms

In case of inhalation:
 Irritant. cough, shortness of breath, shortage of breath, cramp feeling in breast.
 After contact with skin: skin rash, urticaria, redness, Ignition
 May cause sensitisation by skin contact.
 After eye contact: Irritant, conjunctivitis

12. Ecological information

Ecotoxicity

Aquatic toxicity:	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
	Cumene hydroperoxide:
	Algae toxicity: Pseudokirchneriella subcapitata (green algae): ErC 3,1 mg/L/72h, OECD 201
	Daphnia toxicity: Daphnia magna (Big water flea) EC50: 18 mg/L/48h, OECD 202
	Fish toxicity: Oncorhynchus mykiss LC50: 3,9 mg/L/96h, OECD 203
	2-Hydroxyethyl methacrylate
	Algae toxicity: Pseudokirchneriella subcapitata (green algae): EC50 345 mg/L/72h, OECD 201
	Daphnia toxicity: Daphnia magna (Big water flea) EC50: 380 mg/L/48h, OECD 202
	Fish toxicity: Pimephales promelas (fathead minnow) LC50: 227 mg/L/96h, OECD 203
	Cumene
	Algae toxicity: Pseudokirchneriella subcapitata (green algae): ErC 2,6 mg/L/72h, OECD 201
	Daphnia toxicity: Daphnia magna (Big water flea) EC50: 4 mg/L/48h, OECD 202
	Fish toxicity: Oncorhynchus mykiss LC50: 4,8 mg/L/96h, OECD 203

Mobility in soil

adhesives, cured: none Mobility

Persistence and degradability

Further details: Product is biodegradable to a great extent.
2-Hydroxyethyl methacrylate: easily bio-degradable, Degradation: 98 %, OECD 301 E
Cumene hydroperoxide: Degradation: 18 %, OECD 301 E
Cumene: Degradation: 86 %

Additional ecological information

Oxygen demand: BSB: 600000 mg/L
CSB: 1200000 mg/L
Volatile organic compounds (VOC): <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-Hydroxyethyl methacrylate:	TSCA Inventory: listed TSCA HPVC: not listed
Diethyltoluidine:	TSCA: listed
Cumene hydroperoxide:	TSCA Inventory: listed TSCA HPVC: not listed Clean Air Act: SOCMI Chemical: yes Other Environmental Laws: CERCLA: RQ 10 lbs. RCRA Hazardous Wastes: Code U096 SARA Title III Section 313, Toxic Release: Conc. 1.0% / Threshold Standard OSHA Process Safety Management: Threshold 5000 lbs.
Dimethyltoluidine:	TSCA: listed
Cumene:	TSCA Inventory: listed TSCA HPVC: not listed Clean Air Act: Hazardous Air Pollutants: Code XOY SOCMI Chemical: yes Other Environmental Laws: CERCLA: RQ 5000 lbs. RCRA Hazardous Wastes: Code U055 SARA Title III Section 313, Toxic Release: Conc. 1.0% / Threshold Standard NIOSH Recommendations: Occupational Health Guideline: 0159*

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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

National regulations - Great Britain

Hazchem-Code: -

16. Other information

Text for labeling: Contains 10 - 20 % 2-Hydroxyethyl methacrylate, 0.9 - 3 % Diethyltoluidine, 1 - 2.5 % Cumene hydroperoxide, 0.1 - 0.9 % Dimethyltoluidine, 0.1 - 0.5 % Cumene. Safety data sheet available on request.

Hazard rating systems:



NFPA Hazard Rating:

Health: 1 (Slight)

Fire: 1 (Slight)

Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 1 (Slight)

Flammability: 1 (Slight)

Physical Hazard: 0 (Minimal)

Personal Protection: X = Consult your supervisor

HEALTH	1
FLAMMABILITY	1
PHYSICAL HAZARD	0
	X

Reason of change:

Changes in section 1: Address

Date of first version:

6/8/1996

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.