

1. Product and company identification

Product identifier

Trade name: 636K12 - Loctite 245

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

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

Color: blue

clear

Odor: characteristic

Classification: Skin Irritation - Category 2. Eye Irritation - Category 2A.
Specific Target Organ Toxicity (Repeated Exposure) - Category 2.
Aquatic toxicity - chronic - Category 3.

Hazard symbols:



Signal word: **Warning**

Hazard statements:

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

Precautionary statements:

- Do not breathe mist/vapors/spray.
- Avoid release to the environment.
- Wear protective gloves/protective clothing/eye protection.
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- Get medical advice/attention if you feel unwell.
- If eye irritation persists: Get medical advice/attention.

Regulatory status

This material is considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200).

Hazards not otherwise classified

see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Anaerobic sealants and adhesives

Relevant ingredients:

CAS No.	Designation	Concentration	Classification
CAS 80-15-9	Cumene hydroperoxide	< 3 %	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	N,N-Dimethyl-o-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.

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. Take off contaminated clothing and wash it before reuse. First aider: Pay attention to self-protection!
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 problems persist.
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. Subsequently consult an ophthalmologist.
After swallowing:	Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person. Do not induce vomiting. Consult physician.

Most important symptoms/effects, acute and delayed

Causes serious eye irritation. Conjunctivitis.
Lengthy or repeated contact may cause skin irritation.

Information to physician

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range:	> 212 °F
Auto-ignition temperature:	No data available
Suitable extinguishing media:	Extinguishing powder, foam, carbon dioxide
Extinguishing media which must not be used for safety reasons:	full water jet

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 a self-contained breathing apparatus and chemical protective clothing.

6. Accidental release measures

Personal precautions:	Provide adequate ventilation. Avoid contact with skin and eyes. Avoid breathing mist/vapors/spray. Wear appropriate protective equipment. Take off 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. Final cleaning: Remove residues with soap and water.

7. Handling and storage

Handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed.
Avoid contact with skin and eyes. Wear appropriate protective equipment. Take off contaminated clothing and wash it before reuse. Avoid breathing mist/vapors/spray.
Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Have eye wash bottle or eye rinse ready at work place.

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: 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
112945-52-5	Silicon dioxide	USA: IDLH: TWA	3,000 mg/m ³
		USA: NIOSH: TWA	6 mg/m ³
		USA: OSHA: TWA	20 mppcf
		USA: OSHA: TWA	80 mg/m ³ (total dust)

Engineering controls

Provide for good ventilation or exhaust system or work with completely self-contained equipment.
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: => 0.4 mm
Breakthrough time: >480 min.
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Respiratory protection: Use only in well-ventilated areas.
Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded.

General hygiene considerations:

Avoid contact with skin and eyes. Take off contaminated clothing and wash it before reuse. Avoid breathing mist/vapors/spray.

Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Have eye wash bottle or eye rinse ready at work place.

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 68 °F and 101.3 kPa: liquid Color: blue clear
Odor:	characteristic
Odor threshold:	No data available
pH:	3 - 6
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	> 392 °F
Flash point/flash point range:	> 212 °F
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	No data available
Vapor pressure:	at 77 °F: < 0.1 hPa
Vapor density:	No data available
Density:	at 68 °F: 1.08 g/mL
Solubility:	in acetone miscible.
Water solubility:	immiscible
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	No data available
Additional information:	No data available

10. Stability and reactivity

Reactivity:	Refer to subsection "Possibility of hazardous reactions".
Chemical stability:	Stable under recommended storage conditions.
Possibility of hazardous reactions:	No hazardous reaction when handled and stored according to provisions.
Conditions to avoid:	No data available
Incompatible materials:	No data available

Hazardous decomposition products:

No hazardous decomposition products when regulations for storage and handling are observed.

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.

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

Acute toxicity (inhalative): Lack of data.

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: Lack of data.

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): Specific Target Organ Toxicity (Repeated Exposure) -

Category 2 = May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard: Lack of data.

Other information:

Information about cumene hydroperoxide:

LD50 Rat, oral: 382 mg/kg

LD50 Rat, dermal: 530 - 1,060 mg/kg

ATE, dermal: 1,100 mg/kg (Data obtained by expert judgement.)

Symptoms

May cause respiratory irritation. Cough, shortage of breath.

In case of inhalation: May cause irritations. Cough, shortage of breath

In case of ingestion: May cause irritations.

The following symptoms may occur: Gastric and intestinal problems.

After contact with skin: Lengthy or repeated contact may cause skin irritation.

After eye contact:

Upon direct contact with eyes may cause burning, tearing, redness. Conjunctivitis

12. Ecological information

Ecotoxicity

Aquatic toxicity: Harmful to aquatic life with long lasting effects.
 Information about cumene hydroperoxide: Fish toxicity:
 LC50 Oncorhynchus mykiss: 3.9 mg/L/96h (OECD 203)
 Daphnia toxicity:
 EC50 Daphnia magna (Big water flea): 18 mg/L/48h (OECD 202)
 Algae toxicity:
 EC50 Pseudokirchneriella subcapitata (green algae), growth rate: 3.1 mg/L/72h

Mobility in soil

No data available

Persistence and degradability

Further details: No data available

Additional ecological information

Volatile organic compounds (VOC):

3 % by weight

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.

Package

Recommendation: Waste key number:
 150104 metallic packaging.
 150102 Plastic packaging.
 Dispose of waste according to applicable legislation.
 Handle contaminated packages in the same way as the substance itself.

14. Transport information

UN number

ADR/RID, IMDG, IATA-DGR:

not applicable

UN proper shipping name

ADR/RID, IMDG, IATA-DGR:

Not restricted

Transport hazard class(es)

ADR/RID, IMDG, IATA-DGR:

not applicable

Packing group

ADR/RID, IMDG, IATA-DGR:

not applicable

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)

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

Cumene hydroperoxide:

TSCA Inventory: listed

Clean Air Act:

CAA SOCM 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.

N,N-diethyl-p-toluidine:

TSCA Inventory: listed

N,N-Dimethyl-o-toluidine:

TSCA Inventory: listed

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

16. Other information

Text for labeling:

Contains < 3 % Cumene hydroperoxide, < 1 % N,N-diethyl-p-toluidine, < 1 % N,N-Dimethyl-o-toluidine. 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)

Flammability: 1 (Slight)

Physical Hazard: 0 (Minimal)

Personal Protection: X = Consult your supervisor

HEALTH	2
FLAMMABILITY	1
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
 ATE: Acute toxicity estimate
 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 Damage: Eye damage
 Eye Irritation: Eye irritation
 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%
 MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
 OECD: Organisation for Economic Co-operation and Development
 OEL: Occupational Exposure Limit Value
 Organic Peroxide: Organic peroxide
 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
 Skin Corrosion: Skin corrosion
 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
 vPvB: Very persistent and very bioaccumulative
 WEL: Workplace Exposure Limit

Reason of change:

General revision

Date of first version:

5/25/2003

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.