

1. Product and company identification

Product identifier

Trade name: 636K36 - Fast Set Adhesive ergo.Smart.Pen

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

Dept. 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
Color: colorless

Odor: irritant

Classification: Skin Irritation - Category 2; Eye Irritation - Category 2A;
Specific Target Organ Toxicity (Single Exposure) - Category 3;

Hazard symbols:



Signal word:

Warning

Hazard statements:

Causes skin irritation.
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.
 IF ON SKIN: Wash with plenty of water/soap.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 Store in a well-ventilated place. Keep container tightly closed.

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: Adhesive based on cyanoacrylic acid ester

Relevant ingredients:

CAS No.	Designation	Content	Classification
CAS 7085-85-0	Cyanacrylic ester	>= 30 %	Skin Irritation - Category 2. Eye Irritation - Category 2A. Specific Target Organ Toxicity (Single Exposure) - Category 3.

4. First aid measures

General information: Take off immediately all contaminated clothing.

In case of inhalation: Provide fresh air.
 Seek medical aid in case of troubles.

Following skin contact: Immediately clean with water and soap or cleanse with acetone followed by thorough rinsing. If product comes into contact with lips, hold mouth open. Do not allow lips to contact one another.
 Do not peel solidified product off the skin.

After eye contact: Keep eye wide open.
 Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart.
 Afterwards, consult an ophthalmologist immediately.

After swallowing: Do not induce vomiting. Consult physician.

Most important symptoms/effects, acute and delayed

Cyanacrylate - Danger - skin and eyelids will stick together in seconds.

Information to physician

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range:

> 176 °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:

Full water jet

Specific hazards arising from the chemical

In case of fire, cyanides, nitrogen oxides (NOx) and CO2 may be released.

Danger of formation of toxic pyrolysis products.

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.

Environmental precautions:

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

Methods for clean-up:

Soak up with absorbent materials such as sand, siliceous earth, acid- or universal binder.
Store in special closed containers and dispose of according to ordinance.

7. Handling and storage

Handling

Advices on safe handling: Provide adequate ventilation. Do not breathe vapors.

Avoid contact with skin and eyes.

Precautions against fire and explosion:

Keep away from sources of ignition - No smoking.

Specific use(s)

Adhesive for orthopedic procedures.

Storage

Requirements for storerooms and containers:

Keep container tightly closed in a cool place.

Keep container dry. Keep only in the original container.

storage temperature: 41 - 77 °F. Protect from frost, heat and sunlight.

Keep locked up and out of the reach of children.

Hints on joint storage:

Do not store together with alkalis.

8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
7085-85-0	Cyanacrylic ester	USA: ACGIH: STEL	1 ppm
		USA: ACGIH: TWA	0.2 ppm

Engineering controls

Provide good ventilation in the work area.

Where the atmosphere is very dry, the atmospheric moisture level must be raised to at least 50-60% relative humidity.

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: Protective gloves according to OSHA Standard - 29 CFR: 1910.138.
Glove material: Nitrile rubber - Layer thickness: 0,11 mm.
Breakthrough time: >480 min.
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Respiratory protection: Use filter type A (= against vapors of organic substances) according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.

General hygiene considerations:

Cyanacrylate - Danger - skin and eyelids will stick together in seconds.

Keep out of the reach of children.

When using do not eat, drink or smoke.

Keep away from food, drink and animal feedingstuffs.

Wash hands before breaks and after work.

Do not breathe gas/fume/vapour/spray.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Form: liquid Color: colorless
Odor:	irritant
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:	> 176 °F
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	No data available
Vapor pressure:	at 68 °F: Ethyl 2-cyanoacrylate: 0.12 hPa (DIN 51754)
Vapor density:	No data available
Density:	at 68 °F: 1,06 g/ml
Water solubility:	hydrolysis
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	not self-igniting
Thermal decomposition:	No data available
Viscosity, dynamic:	70-120 mPa.s (Brookfield)
Explosive properties:	not applicable

Solvent content:
Solid content:

10. Stability and reactivity

Reactivity:	refer to 10.3
Chemical stability:	Product is stable under normal storage conditions.
Possibility of hazardous reactions	Polymerization along with heat production.
Conditions to avoid:	Heat will be generated if water is added. Reacts violently with water. Protect from frost, heat and sunlight.
Incompatible materials:	Violent reaction with strong alkalis, oxidizing materials and amines. Reacts with alcohols, Acids. and alcohol
Hazardous decomposition products:	In case of fire may be liberated: Cyanide, nitrous fumes (NOx) and carbon monoxide.
Thermal decomposition:	No data available

11. Toxicological information

Toxicological tests

<p>Toxicological effects:</p> <p>Acute toxicity (oral): Lack of data.</p> <p>Acute toxicity (dermal): Lack of data.</p> <p>Acute toxicity (inhalative): Lack of data.</p> <p>Skin corrosion/irritation: Skin Irritation - Category 2 = Causes skin irritation.</p> <p>Serious eye damage/irritation: Eye Irritation - Category 2A = Causes serious eye irritation.</p> <p>Sensitisation to the respiratory tract: Lack of data.</p> <p>Skin sensitisation: Lack of data.</p> <p>Germ cell mutagenicity/Genotoxicity: Lack of data.</p> <p>Carcinogenicity: Lack of data.</p> <p>Reproductive toxicity: Lack of data.</p> <p>Effects on or via lactation: Lack of data.</p> <p>Specific target organ toxicity (single exposure): Specific Target Organ Toxicity (Single Exposure) - Category 3 = May cause respiratory irritation.</p> <p>Specific target organ toxicity (repeated exposure): Lack of data.</p> <p>Aspiration hazard: Lack of data.</p>	<p>Other information:</p> <p>Sensitization: May cause sensitization by inhalation.</p> <p>Cyanacrylate - Danger - skin and eyelids will stick together in seconds.</p>
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Symptoms

In case of inhalation: irritant
 After contact with skin: irritant
 After eye contact: irritant

12. Ecological information

Ecotoxicity

Further details: No data available

Mobility in soil

No data available

Persistence and degradability

Further details: No data available

Additional ecological information

General information: Do not allow to penetrate into soil, waterbodies or drains.

13. Disposal considerations

Product

Recommendation: Dispose of waste according to applicable legislation.
This material and its container must be disposed of as hazardous waste.

Contaminated packaging

Recommendation: Dispose of waste according to applicable legislation.

14. Transport information

USA: Department of Transportation (DOT)

Identification number: UN1993
Proper shipping name: UN 1993, UN 1993, flammable liquids, n.o.s.
(Ethyl 2-cyanoacrylate)
Hazard class or Division: 3
Packing Group: III
Labels: 3
Symbols: G
Special provisions: B1, B52, IB3, T4, TP1, TP29
Packaging – Exceptions: 150
Packaging – Non-bulk: 203
Packaging – Bulk: 242
Quantity limitations – Passenger aircraft / rail: 60 L
Quantity limitations – Cargo only: 220 L
Vessel stowage – Location: A



Sea transport (IMDG)

Proper shipping name: Not restricted
Marine pollutant: no

Air transport (IATA)

UN/ID number: UN 3334
 Proper shipping name: UN 3334, AVIATION REGULATED LIQUID, N.O.S. (Ethyl 2-cyanoacrylate)
 Class or division, Subsidiary risk: Class 9
 Packing Group: III
 Hazard label: Miscellaneous
 Excepted Quantity Code: E1
 Passenger and Cargo Aircraft: Ltd.Qty.: Pack.Instr. Y964 - Max. Net Qty/Pkg. 30 kg G
 Passenger and Cargo Aircraft: Pack.Instr. 964 - Max. Net Qty/Pkg. 450 L
 Cargo Aircraft only: Pack.Instr. 964 - Max. Net Qty/Pkg. 450 L
 Special provisions: A27
 Emergency Response Guide-Code (ERG): 9A

15. Regulatory information

National regulations - U.S. Federal Regulations

Cyanacrylic ester: TSCA Inventory: listed
 TSCA HPVC: not listed

National regulations - U.S. State Regulations

Cyanacrylic ester: California Proposition 65: Not listed.

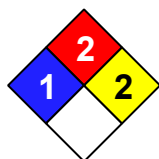
National regulations - Great Britain

Hazchem-Code: -

16. Other information

Text for labeling: Contains >= 30 % Cyanacrylic ester. Safety data sheet available on request.

Hazard rating systems: NFPA Hazard Rating:
 Health: 1 (Slight)
 Fire: 2 (Moderate)
 Reactivity: 2 (Moderate)



HMIS Version III Rating:
 Health: 1 (Slight)
 Flammability: 2 (Moderate)
 Physical Hazard: 2 (Moderate)
 Personal Protection: X = Consult your supervisor

HEALTH	1
FLAMMABILITY	2
PHYSICAL HAZARD	2
	X

Reason of change: Changes in section 1.3: Corporate headquarters

Date of first version: 2/6/2009

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.