

1 Identification of the substance/mixture and of the company/undertaking

Product details

Trade name: EPIGLU®

Reference-no. / Version: 2500/6

Article-No.: EPIGLU01, EPIGLU02, EPIGLU04, EPIGLUOP, EPISDP05, EPISDP10, EPISDP25, EPIGLUSD

Application of the substance / the preparation:

(Please note the application instructions.)

Cyanoacrylate adhesive for medical use.

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

This product may only be used in the manner provided. A liability for improper applications is excluded.

Manufacturer/Supplier:

MEYER - HAAKE GmbH
Medical Innovations
Am Joseph 9
D-61273 Wehrheim

Informing department: Qualitymanagement: ++49 - 6081 / 4461 - 0 (info@meyer-haake.com)

Emergency information: Qualitymanagement: ++49 - 6081 / 4461 - 0

2 Hazards identification

Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

STOT SE 3 H335+H336 May cause respiratory irritation. May cause drowsiness or dizziness.

Classification according to Directive 67/548/EEC or Directive 1999/45/EC



Xi; Irritant

R36/37/38: Irritating to eyes, respiratory system and skin.

Information concerning particular hazards for human and environment:

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

Classification system:

The classification is in line with current EC lists. It is expanded, however, by information from technical literature and by information furnished by supplier companies.

Label elements

Labelling according to Regulation (EC) No 1272/2008

Hazard pictograms



GHS07

Signal word Warning

Hazard-determining components of labelling: Void

Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335+H336 May cause respiratory irritation. May cause drowsiness or dizziness.

Cyanoacrylate. Danger. Bonds skin and eyes in seconds. Keep out of the reach of children.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P321 Specific treatment (see on this label).

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Labelling according to EU guidelines:

The product has been classified and labelled in accordance with EC Directives / Ordinance on Hazardous Materials.

Observe the normal safety regulations when handling chemicals.

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Code letter and hazard designation of product:



Xi Irritant

Hazard-determining components of labelling: --

Risk phrases:

36/37/38 Irritating to eyes, respiratory system and skin.

Safety phrases:

- 2 Keep out of the reach of children.
- 23 Do not breathe fumes.
- 24/25 Avoid contact with skin and eyes.
- 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- 37 Wear suitable gloves.
- 60 This material and its container must be disposed of as hazardous waste.

Special labelling of certain preparations:

Cyanoacrylate. Danger. Bonds skin and eyes in seconds. Keep out of the reach of children.

3 Composition/information on ingredients

Chemical characterization

Description: Mixture consisting of the following components.

Dangerous components:

CAS: 7085-85-0	ethyl 2-cyanoacrylate	Xi R36/37/38	> 75%
EINECS: 230-391-5		Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	

SVHC (substances of very high concern): The product contains no listed substances.

Regulation (EC) No 648/2004 on detergents / Labelling for contents: This product is not under restriction of the regulation of EC 648/2004.

Regulation (EC) No 2032/2003 on biocidal-produkts: This product is not under restriction of the regulation of EC 2032/2003.

Additional information For the wording of the listed risk phrases refer to section 16.

4 First aid measures

General information: Remove the victim immediately from the danger area. If the patient is unwell consult a doctor and present this data sheet.

After inhalation: In case of unconsciousness bring patient into stable side position for transport.

After skin contact: Instantly wash affected parts of the body with water and soap and rinse thoroughly. Seek medical treatment and present this data sheet.

After eye contact: Wash out eyes under running water or with an eye douche for 10 to 15 minutes. Then immediately consult a doctor.

After swallowing: Drink plenty of water and supply plenty of fresh air. Consult a doctor immediately. Do not cause patient to vomit.

Information for doctor: None.

5 Firefighting measures

Suitable extinguishing agents: CO₂, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.

For safety reasons unsuitable extinguishing agents: None.

Special hazards caused by the material, its products of combustion or flue gases: Nitrogen oxides (NO_x)

Protective equipment: No special measures required.

6 Accidental release measures

Person-related safety precautions: Wear protective equipment. Keep unprotected persons away.

Measures for environmental protection: No special measures required.

Measures for cleaning/collecting:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dilute with much water.

Ensure adequate ventilation.

7 Handling and storage

Handling

Information for safe handling:

Keep containers tightly sealed.

Ensure good ventilation/exhaustion at the workplace.

Open and handle container with care.

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Information about protection against explosions and fires: No special measures required.

Storage

Requirements to be met by storerooms and containers:

According to the water pollution class (refer to WGK, item 12), the country-specific regulations for storage of water-polluting substances are to be complied with.

Information about storage in one common storage facility: Do not store together with foodstuffs, semiluxuries or feeding stuffs.

Further information about storage conditions: Protect against frost, severe exposure to the sun and contaminants.

Recommended storage temperature: -18°C to +8 °C

Storage class: Not applicable - valid only in the Federal Republic of Germany.

Specific applications: This produkt may be used only for discribed applications.

8 Exposure controls/personal protection

Additional information about design of technical systems: Provide good workplace ventilation/air extraction.

Components with critical values that require monitoring at the workplace:

CAS No.	Designation of material	%	Type	Value	Unit
7085-85-0	ethyl 2-cyanoacrylate (> 75%)				
WEL	Short-term value: 1.5 mg/m³, 0.3 ppm				

Additional information: The applicable german TRGS 900 (MAK-list) was used as the basis for the preparation and/or revision of this safety data sheet.

Personal protective equipment:

General protective and hygienic measures:

Keep away from foodstuffs, beverages and food.

Instantly remove any soiled and impregnated garments.

Wash hands during breaks and at the end of the work.

Avoid contact with the eyes and skin.

Use a moisturising skin cream after processing the product.

Breathing equipment: Not required.

Protection of hands: The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Material of gloves:

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Nitrile rubber, NBR

Penetration time of glove material: The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:

Neoprene gloves

Not suitable are gloves made of the following materials: Natural rubber, NR

Eye protection: Tightly sealed safety glasses.

Body protection: Protective work clothing.

9 Physical and chemical properties

General Information

Appearance:

Form:	Fluid
Colour:	Colourless
Smell:	Pungent

Change in condition:

Melting point/Melting range: -22°C (DIN ISO 3016)

Boiling point/Boiling range: > 200°C (DIN)

Flash point: > 85°C (DIN 51755 / EN ISO 2719)

Ignition temperature: 485°C (DIN 51794)

Self-inflammability: Product is not self-igniting.

Danger of explosion: Product is not explosive.

Critical values for explosion: Not applicable.

Lower: - Vol % (DIN 51649)

Upper: - Vol % (DIN 51649)

Oxidizing properties: Product is not oxidizing.

Steam pressure at 25°C: 0.5 hPa (DIN 51640)

Density at 20°C: 1.05 g/cm³ (DIN 51757)

Settled apparent density: Not applicable.

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Solubility in / Miscibility with
Water: Polymerises in presence of water.
Organic solvents: Soluble in many organic solvents.

pH-value: Not applicable.

Viscosity:
dynamic: Not determined.
kinematic: Not determined.

Solvent separation test: Not applicable.

Flammable components: - %

Water: 0.0 %

Additional information: None.

10 Stability and reactivity

Conditions to be avoided: No decomposition when properly applied and stored.

Materials to be avoided: Amines, alcohols, water

Dangerous reactions: Reacts with alcohols, amines, aqueous acids and alkalis

Dangerous products of composition: None

Additional information: There is no risk of decomposition or uncontrolled chemical reaction when the specified application conditions are complied with.

11 Toxicological information

Acute toxicity:

LD/LC50 values that are relevant for classification:

Due to § 7 of the animal protection law (FRG), no toxicological examination on living organisms was performed for this product. The following listed data are values from the literature which are available to us of individual ingredients, which do not claim to be exhaustive.

Components	Type	Value	Species
7085-85-0 ethyl 2-cyanoacrylate			
Dermal	LD 50	> 2000 mg/kg	(rabbit)

Specific symptoms in biological assay: We do not have any knowledge of this.

Primary irritant effect:

on the skin: Irritant for skin and mucous membranes.

on the eye: Irritant effect.

Sensitization: No sensitizing effect known.

Subacute to chronic toxicity:

Result: We do not have any toxicological data on this point.

Additional toxicological information:

The product shows the following dangers according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version:

Irritant

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction): None.

12 Ecological information

Information about elimination (persistence and degradability):

Evaluation text: We do not have any data on this point.

Other information: The product has good biodegradable properties. (7d:>80%)

Behaviour in environmental systems:

Mobility and bioaccumulation potential: Does not accumulate in organisms.

Other information: We do not have any data on this point.

Ecotoxicological effects:

Remark: No data available.

Behaviour in sewage processing plants:

Comment: The product does not impair the operation of a sewage plant.

Other information: None.

Additional ecological information:

CSB-value:

7085-85-0 ethyl 2-cyanoacrylate

LD50 > 5000 mg/kg (rat)

According to recipe contains the following heavy metals and compounds according to EC guideline NO. 76/464 EC: None

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General notes:

Due to the consistence and the low watersolubility of the product a bioavailability is not probable.

Water hazard class 1 (Self-assessment): slightly hazardous for water.

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

Results of PBT and vPvB assessment: No effects.

13 Disposal considerations

Product:

Recommendation: Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Waste disposal key number:

The classification in a waste code according to the european waste catalogue (EWC) is to be made in accordance with the regional responsible for waste disposal.

European waste catalogue

08 00 00	WASTES FROM THE MANUFACTURE, FORMULATION, SUPPLY AND USE (MFSU) OF COATINGS (PAINTS, VARNISHES AND VITREOUS ENAMELS), ADHESIVES, SEALANTS AND PRINTING INKS
08 04 00	wastes from MFSU of adhesives and sealants (including waterproofing products)
08 04 09	waste adhesives and sealants containing organic solvents or other dangerous substances

Uncleaned packagings:

Recommendation: Disposal must be made according to official regulations.

Recommended cleaning agent: Water, if necessary with cleaning agent.

Cleaned/completely emptied packaging:

Packaging which does not exhibit any harmful adhering products (e.g. cured or cleaned) can be sent for reprocessing.

14 Transport information

Land transport ADR/RID

ADR/RID-GGVs/E Class: -

Remarks: Water pollutant class: WGK 1 (substance which slightly pollutes water)

Maritime transport IMDG/GGVSea:

IMDG/GGVSea Class: -

Marine pollutant: No

Remarks: None.

Air transport ICAO-TI and IATA-DGR:

ICAO/IATA Class: -

Packaging group:

Packing instructions Passenger: -

Packing instructions cargo: -

Comments: None.

UN "Model Regulation": -

Environmental hazards: -

Transport/Additional information:

No dangerous good according to the upper transport-regulations.

This product may be sent by post.

15 Regulatory information

Designation according to EC guidelines:

VOC (EU): 0,00

VOC (EU): 0.00 %

Remarks: This product is under restriction of the regulation of EC 42/2004.

Chemical safety assessment A Chemical Safety Assessment has not been carried out.

National regulations

Additional classification according to Decree on Hazardous Materials, Annex II: None.

Technical instructions (air):

Class	Share in %
NK	1 - 2

16 Other information

The above details are based on the latest state of our knowledge and do not represent any assurance of product properties. Processing notes for this product are listed in a technical data sheet. Moreover a material compatibility test is to be undertaken with these containers before use of other storage or transport

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containers than those used by the manufacturer.

Existing laws, decrees and regulations, even those which are not stated in this data sheet are to be complied with by the recipient of our products at his own responsibility.

Relevant phrases

The following risk-phrases belong to single-substances of this preparation (chapter 3). Those risk-phrases, which are relevant for the classification of this product, are listed in the chapter 2.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

R36/37/38 Irritating to eyes, respiratory system and skin.

Department issuing data specification sheet:

Ingenieurbüro Jürgen Petry

Heidelsheimer Str. 4

D-76703 Kraichtal

Tel: ++49 7251 - 960 944

FAX: ++49 7251 - 960 946

Contact:

Herr Petry

Tel: ++49 7251 - 960 944

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organization

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

[*] Those chapters marked with(*) were changed to the previous version of this MSDS.

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