

Safety Data Sheet according to Regulation (EC) No. 1907/2006
AESCULAP AG
Revision date: 12.08.2011 Revision no.: 1,03
HISTOACRYL
00250-0012

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

Product identifier

HISTOACRYL

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

Use of the substance/mixture

Adhesive

Details of the supplier of the safety data sheet

AESCULAP AG

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SECTION 2: Hazards identification

Classification of the substance or mixture

This mixture is not classified as dangerous according to Directive 1999/45/EC.

Label elements

Special labelling of certain mixtures

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

Additional advice on labelling

According to the EC hazardous substance regulations in compliance with the EC medicine product regulations this product must not be labelled as a hazardous substance.

Other hazards

Bonds skin and eyes in seconds.

SECTION 3: Composition/information on ingredients

Mixtures

Chemical characterization

One-component adhesive based on butylcyanoacrylate

Hazardous components

EC No.	Chemical name	Quantity
CAS No.	Classification	
REACH No.		
229-552-2	Enbucrilate	90 - 100 %
6606-65-1		

Full text of each relevant R phrase can be found in heading 16.

SECTION 4: First aid measures

Description of first aid measures

General information

Remove and wash contaminated clothing before re-use.

After inhalation

Move to fresh air in case of accidental inhalation of fumes from overheating or combustion.
Refer for medical treatment.

After contact with skin

Do not pull bonded skin apart. It may be gently peeled apart using a blunt object such as a spoon, preferably after soaking in warm soapy water.

Cyanoacrylates release heat during setting. In rare cases, a larger product quantity may develop enough heat to cause burns.

Burns should be treated normally after the adhesive has been removed from the skin.

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If lips are accidentally stuck together apply warm water to the lips and encourage maximum wetting and pressure from saliva inside the mouth.

Peel or roll lips apart. Do not try to pull lips apart with direct opposing action.

After contact with eyes

If the eye is bonded closed, release eyelashes with warm water by covering with a wet cotton pad.

Cyanoacrylate will bond to eye protein and will cause periods of weeping which will help to debond the adhesive.

Keep eye covered until debonding is complete, usually within 1-3 days. Do not force eye open. Medical advice should be sought in case solid particles of cyanoacrylate are trapped behind the eyelid causing thus an abrasive damage.

After ingestion

Make sure that there is no airways obstruction The product will polymerise immediately in the mouth making it almost impossible to swallow it. Saliva will slowly separate the solidified product from the mouth (several hours).

Most important symptoms and effects, both acute and delayed

Bonds skin and eyes in seconds.

Vapours may irritate eyes and the respiratory system.

Indication of any immediate medical attention and special treatment needed

Treat symptoms.

SECTION 5: Firefighting measures

Extinguishing media

Suitable extinguishing media

Foam, carbon dioxide (CO₂), dry chemical, water-spray.

Extinguishing media which must not be used for safety reasons

Full water jet.

Special hazards arising from the substance or mixture

Fire may produce:

Carbon monoxide, carbon dioxide, sulphur oxides and nitrogen oxides (NO_x).

Advice for firefighters

Use breathing apparatus with independent air supply.

Protective suit.

Additional information

Cool containers at risk with water spray jet.

Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes and clothing.

Ensure adequate ventilation.

Use personal protective clothing.

Environmental precautions

Do not discharge into the drains/surface waters/groundwater.

Methods and material for containment and cleaning up

Do not collect spills using clothes. Flood with water in order to terminate the polymerisation and scrape off floor. Hardened material can be disposed of as non-hazardous waste.

Reference to other sections

Observe protective instructions (see Sections 7 and 8).

Information for disposal look up chapter 13.

SECTION 7: Handling and storage

Precautions for safe handling

Advice on safe handling

Ventilation (moderate ventilation) is recommended when larger quantities are used, or where odour problems should become apparent (the odour limit is around 1-2ppm).

In order to minimise the risk of accidental skin or eye contact it is recommended to use automatic dispensing devices.

Keep containers dry and tightly closed to avoid moisture absorption and contamination.

Advice on protection against fire and explosion

No special protective measures against fire required.

Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Store in a cool and shaded area.

Keep only in original container.

Recommended storage temperature: < +22°C

Advice on storage compatibility

Incompatible with:

Oxidizing agents., Bases., Water, amines, alcohols

Further information on storage conditions

Keep away from food, drink and animal feeding stuffs.

Specific end use(s)

Adhesive

SECTION 8: Exposure controls/personal protection

Control parameters

Exposure controls

Protective and hygiene measures

Wash hands before breaks and immediately after handling the product.

When using, do not eat, drink or smoke.

Avoid contact with skin, eyes and clothing.

Take off immediately all contaminated clothing.

Respiratory protection

No personal respiratory protective equipment normally required.

Hand protection

Solvent-resistant gloves (nitrile rubber).

Requirements can vary as a function of the use. Therefore it is necessary to adhere additionally to the recommendations given by the manufacturer of protective gloves.

It should be taken into consideration, that due to the great number of influential factors such as the temperature, the daily durability of chemicals resistant protective gloves may be considerably reduced in practice, compared to the permeation rate assessed according to EN 374.

Eye protection

Tightly fitting goggles.

Eye wash bottle with pure water.

Skin protection

Long sleeved clothing.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	Colourless
Odour:	Ester-like

Test method

Changes in the physical state

Boiling point: > 149 °C

Flash point: 80 - 93,4 °C

Lower explosion limits: n.d.

Ignition temperature: n.d.

Vapour pressure: < 0,3 hPa

Density (at 20 °C): 1,00 - 1,02 g/cm³

Water solubility:
(at 20 °C) polymerised

Solubility in other solvents: Acetone: Soluble

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SECTION 10: Stability and reactivity

Reactivity

No decomposition if stored and applied as directed.

Chemical stability

Stable under normal conditions.

Possibility of hazardous reactions

Reactions with oxidizing agents.

Rapid exothermic polymerisation will occur in the presence of water, amines, alkalis and alcohols.

Conditions to avoid

To avoid thermal decomposition, do not overheat.

Product is sensitive to light and moisture.

Incompatible materials

Bases., Oxidizing agents., Water, amines, alcohols

Hazardous decomposition products

Carbon monoxide (CO), carbon dioxide (CO₂) and nitrogen oxides (NO_x).

SECTION 11: Toxicological information

Information on toxicological effects

Acute toxicity

LD50/oral/rat: > 5000 mg/kg

LD50/dermal/rabbit: > 2000 mg/kg

Irritation and corrosivity

Skin irritation: Not classified.

Eye irritation: Not classified.

Sensitizing effects

Not classified.

Severe effects after repeated or prolonged exposure

STOT - Single exposure: Not classified.

STOT - Repeated exposure: Not classified.

Aspiration hazard: Not classified.

Carcinogenic/mutagenic/toxic effects for reproduction

Carcinogenicity: Not classified.

Mutagenicity: Not classified.

Teratogenicity Not classified.

Additional information on tests

Classification in compliance with the assessment procedure specified in the EC guidelines 1999/45/EG.

Empirical data on effects on humans

Bonds skin and eyes in seconds.

Vapours may irritate eyes and the respiratory system.

SECTION 12: Ecological information

Toxicity

Ecological data are not available.

Persistence and degradability

No data available.

Bioaccumulative potential

No data available.

Mobility in soil

No data available.

Results of PBT and vPvB assessment

No data available.

Other adverse effects

No data available.

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Further information

Do not flush into surface water or sanitary sewer system.

SECTION 13: Disposal considerations

Waste treatment methods

Advice on disposal

Where possible recycling is preferred to disposal.
Can be incinerated, when in compliance with local regulations.

Waste disposal number of waste from residues/unused products

180106 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care); wastes from natal care, diagnosis, treatment or prevention of disease in humans; chemicals consisting of or containing dangerous substances
Classified as hazardous waste.

Contaminated packaging

Empty containers should be taken for local recycling, recovery or waste disposal.
Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse.
Packaging that cannot be cleaned should be disposed of like the product.

SECTION 14: Transport information

Land transport (ADR/RID)

Other applicable information (land transport)

Not dangerous according the ADR/RID.

Marine transport

UN proper shipping name:

Not classified as dangerous in the meaning of sea transport regulations.

Air transport

UN/ID number:

UN3334

UN proper shipping name:

AVIATION REGULATED LIQUID, N.O.S. (Cyanoacrylate ester)

Transport hazard class(es):

9

Hazard label:

9



Limited quantity Passenger:	Y964 / 30 kg G
IATA-packing instructions - Passenger:	964
IATA-max. quantity - Passenger:	100 L
IATA-packing instructions - Cargo:	964
IATA-max. quantity - Cargo:	220 L

Environmental hazards

Dangerous for the environment: no

Special precautions for user

Handle in accordance with good industrial hygiene and safety practice.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

The transport takes place only in approved and appropriate packaging.

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

1999/13/EC (VOC): < 3 %

National regulatory information

Water contaminating class (D): -- not water contaminating

Chemical Safety Assessment

For this substance a chemical safety assessment has not been carried out.

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SECTION 16: Other information

Further Information

Data of items 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities.

The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge.

The delivery specifications are contained in the corresponding product sheet.

This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

(n.a. = not applicable; n.d. = not determined)

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)