



## Safety Data Sheet according to Regulation (EC) No 1907/2006

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LOCTITE 4013 GAP FILLING MED GRADE ADH Prism® 4013  
Medical Device Ins

SDS No. : 153567  
V002.6  
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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

LOCTITE 4013 GAP FILLING MED GRADE ADH Prism® 4013 Medical Device Ins

#### Contains:

Ethyl 2-cyanoacrylate

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Intended use:  
Adhesive

#### 1.3. Details of the supplier of the safety data sheet

Henkel Ltd  
Wood Lane End  
HP2 4RQ Hemel Hempstead

Great Britain

Phone: +44 1442 278000  
Fax-no.: +44 1442 278071

ua-productsafety.uk@henkel.com

#### 1.4. Emergency telephone number

24 Hours Emergency Tel: +44 (0)1442 278497

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification (CLP):

Skin irritation	Category 2
H315 Causes skin irritation.	
Serious eye irritation	Category 2
H319 Causes serious eye irritation.	
Specific target organ toxicity - single exposure	Category 3
H335 May cause respiratory irritation.	
Target organ: respiratory tract irritation	

#### 2.2. Label elements

##### Label elements (CLP):

Hazard pictogram:



<b>Signal word:</b>	Warning
<b>Hazard statement:</b>	H315 Causes skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation.
<b>Supplemental information</b>	EUH202 Cyanoacrylate. Danger. Bonds skin and eyes in seconds. Keep out of the reach of children.
<b>Precautionary statement: Prevention</b>	P261 Avoid breathing vapours. P280 Wear protective gloves/eye protection.
<b>Precautionary statement: Response</b>	P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention.
<b>Precautionary statement: Disposal</b>	P501 Dispose of waste and residues in accordance with local authority requirements.

**2.3. Other hazards**

None if used properly.

Not fulfilling Persistent, Bioaccumulative and Toxic (PBT), very Persistent and very Bioaccumulative (vPvB) criteria.

**SECTION 3: Composition/information on ingredients****3.2. Mixtures****General chemical description:**

Cyanoacrylate Adhesive

**Declaration of the ingredients according to CLP (EC) No 1272/2008:**

Hazardous components CAS-No.	EC Number REACH-Reg No.	content	Classification
Ethyl 2-cyanoacrylate 7085-85-0	230-391-5 01-2119527766-29	80- < 100 %	Eye Irrit. 2 H319 STOT SE 3 H335 Skin Irrit. 2 H315
Hydroquinone 123-31-9	204-617-8 01-2119524016-51	0,01- < 0,1 %	Aquatic Acute 1 H400 Aquatic Chronic 1 H410 Carc. 2 H351 Muta. 2 H341 Acute Tox. 4; Oral H302 Eye Dam. 1 H318 Skin Sens. 1 H317 M factor (Acute Aquat Tox): 10

For full text of the H - statements and other abbreviations see section 16 "Other information".

Substances without classification may have community workplace exposure limits available.

**SECTION 4: First aid measures****4.1. Description of first aid measures**

**Inhalation:**

Move to fresh air, consult doctor if complaint persists.

**Skin contact:**

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 give off heat on solidification. In rare cases a large drop will generate enough heat to cause a burn.

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

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 the lips apart with direct opposing action.

**Eye contact:**

If the eye is bonded closed, release eyelashes with warm water by covering with wet 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 trapped behind the eyelid cause any abrasive damage.

**Ingestion:**

Ensure that breathing passages are not obstructed. The product will polymerise immediately in the mouth making it almost impossible to swallow. Saliva will slowly separate the solidified product from the mouth (several hours).

**4.2. Most important symptoms and effects, both acute and delayed**

EYE: Irritation, conjunctivitis.

SKIN: Redness, inflammation.

RESPIRATORY: Irritation, coughing, shortness of breath, chest tightness.

**4.3. Indication of any immediate medical attention and special treatment needed**

See section: Description of first aid measures

## SECTION 5: Firefighting measures

**5.1. Extinguishing media**

**Suitable extinguishing media:**

Foam, extinguishing powder, carbon dioxide.

Fine water spray

**Extinguishing media which must not be used for safety reasons:**

High pressure waterjet

**5.2. Special hazards arising from the substance or mixture**

In the event of a fire, carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>) and nitrogen oxides (NO<sub>x</sub>) can be released.

Irritating organic vapours.

**5.3. Advice for firefighters**

Wear self-contained breathing apparatus and full protective clothing, such as turn-out gear.

**Additional information:**

In case of fire, keep containers cool with water spray.

## SECTION 6: Accidental release measures

**6.1. Personal precautions, protective equipment and emergency procedures**

Avoid contact with skin and eyes.

Ensure adequate ventilation.

Wear protective equipment.

**6.2. Environmental precautions**

Do not empty into drains / surface water / ground water.

**6.3. Methods and material for containment and cleaning up**

Do not use cloths for mopping up. Flood with water to complete polymerization and scrape off the floor. Cured material can be disposed of as non-hazardous waste.

**6.4. Reference to other sections**

See advice in section 8

**SECTION 7: Handling and storage****7.1. Precautions for safe handling**

Ventilation (low level) is recommended when using large volumes

Use of dispensing equipment is recommended to minimise the risk of skin or eye contact

Avoid skin and eye contact.

See advice in section 8

Hygiene measures:

Wash hands before work breaks and after finishing work.

Do not eat, drink or smoke while working.

Good industrial hygiene practices should be observed.

**7.2. Conditions for safe storage, including any incompatibilities**

Refer to Technical Data Sheet

**7.3. Specific end use(s)**

Adhesive

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****Occupational Exposure Limits**

Valid for  
Great Britain

Ingredient [Regulated substance]	ppm	mg/m <sup>3</sup>	Value type	Short term exposure limit category / Remarks	Regulatory list
Ethyl 2-cyanoacrylate 7085-85-0 [ETHYL CYANOACRYLATE]	0,3	1,5	Short Term Exposure Limit (STEL):		EH40 WEL
Hydroquinone 123-31-9 [HYDROQUINONE]		0,5	Time Weighted Average (TWA):		EH40 WEL

**Occupational Exposure Limits**

Valid for  
Ireland

Ingredient [Regulated substance]	ppm	mg/m <sup>3</sup>	Value type	Short term exposure limit category / Remarks	Regulatory list
Ethyl 2-cyanoacrylate 7085-85-0 [ETHYL CYANOACRYLATE]	0,2		Time Weighted Average (TWA):		IR_OEL
Hydroquinone 123-31-9 [HYDROQUINONE]		0,5	Time Weighted Average (TWA):		IR_OEL

**Predicted No-Effect Concentration (PNEC):**

Name on list	Environmental Compartment	Exposure period	Value				Remarks
			mg/l	ppm	mg/kg	others	
Hydroquinone 123-31-9	aqua (freshwater)		0,114 µg/l				
Hydroquinone 123-31-9	aqua (marine water)		0,0114 µg/l				
Hydroquinone 123-31-9	sediment (freshwater)				0,98 µg/kg		
Hydroquinone 123-31-9	sediment (marine water)				0,097 µg/kg		
Hydroquinone 123-31-9	aqua (intermittent releases)		0,00134 mg/l				
Hydroquinone 123-31-9	soil				0,129 µg/kg		
Hydroquinone 123-31-9	sewage treatment plant (STP)		0,71 mg/l				

**Derived No-Effect Level (DNEL):**

Name on list	Application Area	Route of Exposure	Health Effect	Exposure Time	Value	Remarks
Ethyl 2-cyanoacrylate 7085-85-0	Workers	Inhalation	Long term exposure - local effects		9,25 mg/m <sup>3</sup>	
Ethyl 2-cyanoacrylate 7085-85-0	Workers	Inhalation	Long term exposure - systemic effects		9,25 mg/m <sup>3</sup>	
Ethyl 2-cyanoacrylate 7085-85-0	General population	Inhalation	Long term exposure - local effects		9,25 mg/m <sup>3</sup>	
Ethyl 2-cyanoacrylate 7085-85-0	General population	Inhalation	Long term exposure - systemic effects		9,25 mg/m <sup>3</sup>	
Hydroquinone 123-31-9	Workers	dermal	Long term exposure - systemic effects		128 mg/kg	
Hydroquinone 123-31-9	Workers	Inhalation	Long term exposure - systemic effects		7 mg/m <sup>3</sup>	
Hydroquinone 123-31-9	Workers	Inhalation	Long term exposure - local effects		1 mg/m <sup>3</sup>	
Hydroquinone 123-31-9	General population	dermal	Long term exposure - systemic effects		64 mg/kg	
Hydroquinone 123-31-9	General population	Inhalation	Long term exposure - systemic effects		1,74 mg/m <sup>3</sup>	
Hydroquinone 123-31-9	General population	Inhalation	Long term exposure - local effects		0,5 mg/m <sup>3</sup>	

**Biological Exposure Indices:**

None

**8.2. Exposure controls:**

Engineering controls:

Ensure good ventilation/extraction.

**Respiratory protection:**

Ensure adequate ventilation.

An approved mask or respirator fitted with an organic vapour cartridge should be worn if the product is used in a poorly ventilated area

Filter type: A (EN 14387)

**Hand protection:**

Chemical-resistant protective gloves (EN 374).

Suitable materials for short-term contact or splashes (recommended: at least protection index 2, corresponding to > 30 minutes permeation time as per EN 374):

nitrile rubber (NBR;  $\geq 0.4$  mm thickness)

Suitable materials for longer, direct contact (recommended: protection index 6, corresponding to > 480 minutes permeation time as per EN 374):

nitrile rubber (NBR;  $\geq 0.4$  mm thickness)

This information is based on literature references and on information provided by glove manufacturers, or is derived by analogy with similar substances. Please note that in practice the working life of chemical-resistant protective gloves may be considerably shorter than the permeation time determined in accordance with EN 374 as a result of the many influencing factors (e.g. temperature). If signs of wear and tear are noticed then the gloves should be replaced.

Polyethylene or polypropylene gloves are recommended when using large volumes.

Do not use PVC, rubber or nylon gloves.

Please note that in practice the working life of chemical resistant gloves may be considerably reduced as a result of many influencing factors (e.g. temperature). Suitable risk assessment should be carried out by the end user. If signs of wear and tear are noticed then the gloves should be replaced.

The use of chemical resistant gloves such as Neoprene or Natural Rubber is recommended

**Eye protection:**

Safety glasses with sideshields or chemical safety goggles should be worn if there is a risk of splashing.

Protective eye equipment should conform to EN166.

**Skin protection:**

Wear suitable protective clothing.

Protective clothing should conform to EN 14605 for liquid splashes or to EN 13982 for dusts.

**Advices to personal protection equipment:**

The information provided on personal protective equipment is for guidance purposes only. A full risk assessment should be conducted prior to using this product to determine the appropriate personal protective equipment to suit local conditions. Personal protective equipment should conform to the relevant EN standard.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Appearance	liquid
	Colorless
Odor	Irritating
Odour threshold	No data available / Not applicable
pH	No data available / Not applicable
Melting point	No data available / Not applicable
Solidification temperature	No data available / Not applicable
Initial boiling point	> 149 °C (> 300.2 °F)
Flash point	65 - 93 °C (149 - 199.4 °F); Tagliabue closed cup
Evaporation rate	No data available / Not applicable
Flammability	No data available / Not applicable
Explosive limits	No data available / Not applicable
Vapour pressure	< 0,300000 mbar
Vapour pressure (50 °C (122 °F))	< 700 mbar
Relative vapour density:	No data available / Not applicable
Density ( $\rho$ )	1,05 g/cm <sup>3</sup>
Bulk density	No data available / Not applicable

Solubility	No data available / Not applicable
Solubility (qualitative) (Solvent: Water)	Polymerises in presence of water.
Partition coefficient: n-octanol/water	No data available / Not applicable
Auto-ignition temperature	No data available / Not applicable
Decomposition temperature	No data available / Not applicable
Viscosity	No data available / Not applicable
Viscosity (kinematic)	No data available / Not applicable
Explosive properties	No data available / Not applicable
Oxidising properties	No data available / Not applicable

## 9.2. Other information

No data available / Not applicable

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

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

### 10.2. Chemical stability

Stable under recommended storage conditions.

### 10.3. Possibility of hazardous reactions

See section reactivity

### 10.4. Conditions to avoid

Stable under normal conditions of storage and use.

### 10.5. Incompatible materials

See section reactivity.

### 10.6. Hazardous decomposition products

None if used for intended purpose.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

#### General toxicological information:

The mixture is classified based on the available hazard information for the ingredients as defined in the classification criteria for mixtures for each hazard class or differentiation in Annex I to Regulation (EC) No 1272/2008. Relevant available health/ecological information for the substances listed under Section 3 is provided in the following.

#### STOT-single exposure:

May cause respiratory irritation.

#### Oral toxicity:

Cyanoacrylates are considered to have relatively low toxicity. Acute oral LD50 is >5000mg/kg (rat). It is almost impossible to swallow as it rapidly polymerises in the mouth.

#### Inhalative toxicity:

Prolonged exposure to high concentrations of vapours may lead to chronic effects in sensitive individuals  
In dry atmosphere with < 50% humidity, vapours may irritate the eyes and respiratory system

#### Skin irritation:

Causes skin irritation.  
Bonds skin in seconds. Considered to be of low toxicity: acute dermal LD50 (rabbit)>2000mg/kg  
Due to polymerisation at the skin surface allergic reaction is unlikely to occur

#### Eye irritation:

Causes serious eye irritation.  
Liquid product will bond eyelids. In a dry atmosphere (RH<50%) vapours may cause irritation and lachrymatory effect

**Acute oral toxicity:**

Hazardous components CAS-No.	Value type	Value	Route of application	Exposure time	Species	Method
Ethyl 2-cyanoacrylate 7085-85-0	LD50	> 5.000 mg/kg	oral		rat	OECD Guideline 401 (Acute Oral Toxicity)
Hydroquinone 123-31-9	LD50	367 mg/kg	oral		rat	OECD Guideline 401 (Acute Oral Toxicity)

**Acute dermal toxicity:**

Hazardous components CAS-No.	Value type	Value	Route of application	Exposure time	Species	Method
Ethyl 2-cyanoacrylate 7085-85-0	LD50	> 2.000 mg/kg	dermal		rabbit	OECD Guideline 402 (Acute Dermal Toxicity)

**Skin corrosion/irritation:**

Hazardous components CAS-No.	Result	Exposure time	Species	Method
Ethyl 2-cyanoacrylate 7085-85-0	slightly irritating	24 h	rabbit	OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

**Serious eye damage/irritation:**

Hazardous components CAS-No.	Result	Exposure time	Species	Method
Ethyl 2-cyanoacrylate 7085-85-0	irritating	72 h	rabbit	OECD Guideline 405 (Acute Eye Irritation / Corrosion)

**Respiratory or skin sensitization:**

Hazardous components CAS-No.	Result	Test type	Species	Method
Ethyl 2-cyanoacrylate 7085-85-0	not sensitising		guinea pig	not specified
Hydroquinone 123-31-9	sensitising	Guinea pig maximisation test	guinea pig	not specified

**Germ cell mutagenicity:**

Hazardous components CAS-No.	Result	Type of study / Route of administration	Metabolic activation / Exposure time	Species	Method
Ethyl 2-cyanoacrylate 7085-85-0	negative	bacterial reverse mutation assay (e.g Ames test)			OECD Guideline 471 (Bacterial Reverse Mutation Assay)
	negative	mammalian cell gene mutation assay	with and without		OECD Guideline 476 (In vitro Mammalian Cell Gene Mutation Test)
	negative	in vitro mammalian chromosome aberration test	with and without		OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test)
Hydroquinone 123-31-9	negative	bacterial reverse mutation assay (e.g Ames test)	with and without		EU Method B.13/14 (Mutagenicity)

**Repeated dose toxicity**

Hazardous components CAS-No.	Result	Route of application	Exposure time / Frequency of treatment	Species	Method
Hydroquinone 123-31-9	NOAEL= $\geq$ 250 mg/kg	oral: gavage	14 days 5 days/week. 12 doses	rat	OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity in Rodents)
Hydroquinone 123-31-9	LOAEL= $\leq$ 500 mg/kg	oral: gavage	14 days 5 days/week. 12 doses	rat	OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity in Rodents)



## SECTION 12: Ecological information

### General ecological information:

The mixture is classified based on the available hazard information for the ingredients as defined in the classification criteria for mixtures for each hazard class or differentiation in Annex I to Regulation (EC) No 1272/2008. Relevant available health/ecological information for the substances listed under Section 3 is provided in the following.

Biological and Chemical Oxygen Demands (BOD and COD) are insignificant.

### 12.1. Toxicity

#### Ecotoxicity:

Do not empty into drains / surface water / ground water.

Hazardous components CAS-No.	Value type	Value	Acute Toxicity Study	Exposure time	Species	Method
Hydroquinone 123-31-9	LC50	0,638 mg/l	Fish	96 h	Oncorhynchus mykiss	OECD Guideline 203 (Fish, Acute Toxicity Test)
Hydroquinone 123-31-9	EC50	0,134 mg/l	Daphnia	48 h	Daphnia magna	OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)
Hydroquinone 123-31-9	EC50	0,335 mg/l	Algae	72 h	Selenastrum capricornutum (new name: Pseudokirchneriella subcapitata)	OECD Guideline 201 (Alga, Growth Inhibition Test) not specified
Hydroquinone 123-31-9	EC 50	0,038 mg/l	Bacteria	30 min		
Hydroquinone 123-31-9	NOEC	0,0057 mg/l	chronic Daphnia	21 d	Daphnia magna	OECD 211 (Daphnia magna, Reproduction Test)

### 12.2. Persistence and degradability

#### Persistence and Biodegradability:

The product is not biodegradable.

Hazardous components CAS-No.	Result	Route of application	Degradability	Method
Ethyl 2-cyanoacrylate 7085-85-0		aerobic	57 %	OECD Guideline 301 D (Ready Biodegradability: Closed Bottle Test)
Hydroquinone 123-31-9	readily biodegradable	aerobic	75 - 81 %	EU Method C.4-E (Determination of the "Ready" Biodegradability Closed Bottle Test)

### 12.3. Bioaccumulative potential / 12.4. Mobility in soil

#### Mobility:

Cured adhesives are immobile.

#### Bioaccumulative potential:

No data available for the product.

Hazardous components CAS-No.	LogPow	Bioconcentration factor (BCF)	Exposure time	Species	Temperature	Method
Ethyl 2-cyanoacrylate 7085-85-0	0,776				22 °C	EU Method A.8 (Partition Coefficient)
Hydroquinone 123-31-9	0,59					EU Method A.8 (Partition Coefficient)

### 12.5. Results of PBT and vPvB assessment

Hazardous components CAS-No.	PBT/vPvB

Hydroquinone 123-31-9	Not fulfilling Persistent, Bioaccumulative and Toxic (PBT), very Persistent and very Bioaccumulative (vPvB) criteria.
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### 12.6. Other adverse effects

No data available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Product disposal:

Dispose of in accordance with local and national regulations.

Collection and delivery to recycling enterprise or other registered elimination institution.

Contribution of this product to waste is very insignificant in comparison to article in which it is used

Disposal of uncleaned packages:

After use, tubes, cartons and bottles containing residual product should be disposed of as chemically contaminated waste in an authorised legal land fill site or incinerated.

Disposal must be made according to official regulations.

Waste code

08 04 09 waste adhesives and sealants containing organic solvents and other dangerous substances

The valid EWC waste code numbers are source-related. The manufacturer is therefore unable to specify EWC waste codes for the articles or products used in the various sectors. The EWC codes listed are intended as a recommendation for users. We will be happy to advise you.

**SECTION 14: Transport information****14.1. UN number**

ADR	Not dangerous goods
RID	Not dangerous goods
ADN	Not dangerous goods
IMDG	Not dangerous goods
IATA	3334

**14.2. UN proper shipping name**

ADR	Not dangerous goods
RID	Not dangerous goods
ADN	Not dangerous goods
IMDG	Not dangerous goods
IATA	Aviation regulated liquid, n.o.s. (Cyanoacrylate ester)

**14.3. Transport hazard class(es)**

ADR	Not dangerous goods
RID	Not dangerous goods
ADN	Not dangerous goods
IMDG	Not dangerous goods
IATA	9

**14.4. Packing group**

ADR	Not dangerous goods
RID	Not dangerous goods
ADN	Not dangerous goods
IMDG	Not dangerous goods
IATA	III

**14.5. Environmental hazards**

ADR	not applicable
RID	not applicable
ADN	not applicable
IMDG	not applicable
IATA	not applicable

**14.6. Special precautions for user**

ADR	not applicable
RID	not applicable
ADN	not applicable
IMDG	not applicable
IATA	Primary packs containing less than 500ml are unregulated by this mode of transport and may be shipped unrestricted.

**14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

not applicable

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

VOC content < 3,00 %  
(2010/75/EC)

### 15.2. Chemical safety assessment

A chemical safety assessment has been carried out.

## SECTION 16: Other information

The labelling of the product is indicated in Section 2. The full text of all abbreviations indicated by codes in this safety data sheet are as follows:

- H302 Harmful if swallowed.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H318 Causes serious eye damage.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H341 Suspected of causing genetic defects.
- H351 Suspected of causing cancer.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.

### Further information:

This information is based on our current level of knowledge and relates to the product in the state in which it is delivered. It is intended to describe our products from the point of view of safety requirements and is not intended to guarantee any particular properties.

**Relevant changes in this safety data sheet are indicated by vertical lines at the left margin in the body of this document. Corresponding text is displayed in a different color on shadowed fields.**

## Annex - Exposure Scenarios:

Exposure Scenarios for ethyl 2-cyanoacrylate can be downloaded under the following link:  
[http://mysds.henkel.com/mysds/.470833..en.ANNEX\\_DE.15743123.0.DE.pdf](http://mysds.henkel.com/mysds/.470833..en.ANNEX_DE.15743123.0.DE.pdf)  
Alternatively they can be accessed on the internet site [www.mysds.henkel.com](http://www.mysds.henkel.com) by entering number 470833.