

LOCTITE[®] 4601™

December 2020

PRODUCT DESCRIPTION

LOCTITE[®] 4601[™] provides the following product characteristics:

Technology	Cyanoacrylate		
Chemical Type	Alkoxyethyl cyanoacrylate		
Appearance (uncured)	Transparent, colorless to light yellow liquid ^{LMS}		
Components	One part - requires no mixing		
Viscosity	Medium		
Cure	Humidity		
Application	Bonding		
Key Substrates	Metals , Plastics and Elastomers		

LOCTITE[®] 4601[™] has low odor and low blooming properties and is particularly suitable for applications where vapor control is difficult. Suitable for use in the assembly of **disposable medical devices**.

ISO-10993

LOCTITE[®] 4601[™] has been tested to Henkel's test protocols based on ISO 10993 biocompatibility standards, as a means to assist in the selection of products for use in the medical device industry.

TYPICAL PROPERTIES OF UNCURED MATERIAL

Specific Gravity @ 25 °C 1.1
Viscosity, Brookfield - LVF, 25 °C, mPa·s (cP):
Spindle 1, speed 30 rpm 30 to 60^{LMS}
Flash Point - See SDS

TYPICAL CURING PERFORMANCE

Under normal conditions, the atmospheric moisture initiates the curing process. Although full functional strength is developed in a relatively short time, curing continues for at least 24 hours before full chemical/solvent resistance is developed.

Cure Speed vs. Substrate

The rate of cure will depend on the substrate used. The table below shows the fixture time achieved on different materials at 22 $^{\circ}$ C / 50 % relative humidity. This is defined as the time to develop a shear strength of 0.1 N/mm² .

Fixture Time, seconds:

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Steel (degreased)	30 to 70
Aluminum	5 to 20
Zinc dichromate	60 to 180
Neoprene	<5
Rubber, nitrile	<5
ABS	20 to 60
PVC	20 to 50
Polycarbonate	20 to 60

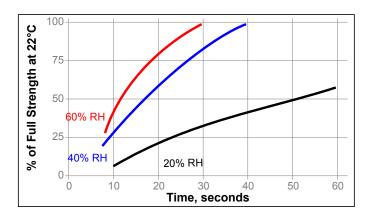
Phenolic 30 to 60

Cure Speed vs. Bond Gap

The rate of cure will depend on the bondline gap. Thin bond lines result in high cure speeds, increasing the bond gap will decrease the rate of cure.

Cure Speed vs. Humidity

The rate of cure will depend on the ambient relative humidity. The following graph shows the tensile strength developed with time on Buna N rubber at different levels of humidity.



Cure Speed vs. Activator

Where cure speed is unacceptably long due to large gaps, applying activator to the surface will improve cure speed. However, this can reduce ultimate strength of the bond and therefore testing is recommended to confirm effect.

TYPICAL PROPERTIES OF CURED MATERIAL

After 24 hours @ 22 °C

Physical Properties:

Coefficient of Thermal Expansion, ISO 11359-2, K⁻¹

Coefficient of Thermal Conductivity, ISO 8302, W/(m·K)

Glass Transition Temperature, ASTM E 228, °C 130

Electrical Properties:

Dielectric Constant / Dissipation Factor, IEC 60250: 0.1 kHz 2.65 / <0.02 1 kHz 2.75 / <0.02 10 kHz 2.75 / <0.02 Volume Resistivity, IEC 60093, Ω ·cm 10×10¹⁵

Volume Resistivity, IEC 60093, Ω ·cm 10×10¹⁵ Surface Resistivity, IEC 60093, Ω 10×10¹⁵ Dielectric Breakdown Strength, 25

IEC 60243-1, kV/mm



TYPICAL PERFORMANCE OF CURED MATERIAL Adhesive Properties

After 24 hours @ 22 °C Lap Shear Strength, : Steel (grit blasted) N/mm² 14 to 22 (psi) (2,030 to 3,190) Aluminum (etched) N/mm² 9 to 15 (1,305 to 2,175) (psi) Zinc dichromate N/mm² 4 to 10 (580 to 1,450) (psi) **ABS** N/mm² 6 to 20 (870 to 2,900) (psi) **PVC** N/mm² 2 to 8 (290 to 1,160) (psi) Polycarbonate N/mm² 3 to 10 (435 to 1,450) (psi) Phenolic N/mm² 5 to 15 (psi) (725 to 2,175) Neoprene N/mm² 5 to 15 (725 to 2,175) (isg) Nitrile N/mm² 5 to 15 (725 to 2,175) (psi)

Tensile Strength, ISO 6922:

Steel (grit blasted)

N/mm² 10 to 25
(psi) (1,450 to 3,625)

Buna-N N/mm² 5 to 15 (psi) (725 to 2,175)

After 10 seconds @ 22 °C Tensile Strength, ISO 6922:

Buna-N $N/mm^2 \ge 4.5^{LMS}$ (psi) (≥ 655)

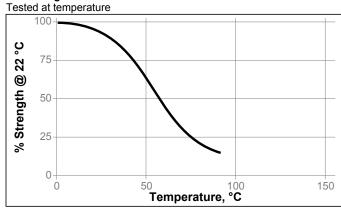
TYPICAL ENVIRONMENTAL RESISTANCE

After 1 week @ 22 °C

Lap Shear Strength, ISO 4587:

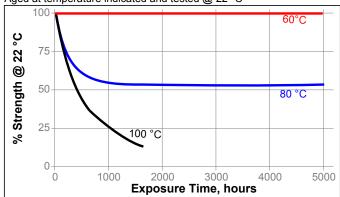
Mild steel (grit blasted)

Hot Strength



Heat Aging

Aged at temperature indicated and tested @ 22 °C



Chemical/Solvent Resistance

Aged under conditions indicated and tested @ 22 °C.

		% of initial strength		
Environment	°C	100 h	500 h	1000 h
Motor oil (MIL-L-46152)	40	75	75	65
Gasoline	22	100	90	75
Ethanol	22	100	90	90
Isopropanol	22	90	90	90
Freon TA	22	100	100	100
Heat/humidity 95% RH	40	15	0	0
Heat/humidity 95% RH on polycarbonate	40	100	100	100

Effects of Sterilization

In general, products similiar in composition to LOCTITE[®] 4601[™] subjected to standard sterilization methods, such as EtO and Gamma Radiation (25 to 50 kiloGrays cumulative) show excellent bond strength retention. LOCTITE[®] 4601[™] maintains bond strength after 1 cycle of steam autoclave. It is recommended that customers test specific parts after subjecting them to the preferred sterilization method. Consult with Loctite[®] for a product recommendation if your device will see more than 3 sterilization cycles.

GENERAL INFORMATION

This product is not recommended for use in pure oxygen and/or oxygen rich systems and should not be selected as a sealant for chlorine or other strong oxidizing materials.

For safe handling information on this product, consult the Safety Data Sheet (SDS).

Directions For Use:

- For best performance bond surfaces should be clean and free from grease.
- 2. This product performs best in thin bond gaps (0.05 mm).
- 3. Excess adhesive can be dissolved with Loctite cleanup solvents, nitromethane or acetone.

Loctite Material Specification^{LMS}

LMS dated January 29, 2003. Test reports for each batch are available for the indicated properties. LMS test reports include selected QC test parameters considered appropriate to specifications for customer use. Additionally, comprehensive controls are in place to assure product quality and consistency. Special customer specification requirements may be coordinated through Henkel Quality.

Storage

Store product in the unopened container in a dry location. Storage information may be indicated on the product container labeling.

Optimal Storage: 2 °C to 8 °C. Storage below 2 °C or greater than 8 °C can adversely affect product properties. Material removed from containers may be contaminated during use. Do not return product to the original container. Henkel Corporation cannot assume responsibility for product which has been contaminated or stored under conditions other than those previously indicated. If additional information is required, please contact your local Henkel Representative.

Conversions

(°C x 1.8) + 32 = °F kV/mm x 25.4 = V/mil mm / 25.4 = mil N x 0.225 = lb N/mm x 5.71 = lb/in N/mm² x 145 = psi MPa x 145 = psi N·m x 8.851 = lb·in N·m x 0.738 = lb·ft N·mm x 0.142 = oz·in mPa·s = cP

Disclaimer

The information provided in this Technical Data Sheet (TDS) including the recommendations for use and application of the product are based on our knowledge and experience of the product as at the date of this TDS. The product can have a variety of different applications as well as differing application and working conditions in your environment that are beyond our control. Henkel is, therefore, not liable for the suitability of our product for the production processes and conditions in respect of which you use them, as well as the intended applications and results. We strongly recommend that you carry out your own prior trials to confirm such suitability of our product. Any liability in respect of the information in the Technical Data Sheet or any other written or oral recommendation(s) regarding the concerned product is excluded, except if otherwise explicitly agreed and except in relation to death or personal injury caused by our negligence and any liability under any applicable mandatory product liability law.

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Reference 1.4



Revision Number: 003.2 Issue date: 05/31/2018

1. PRODUCT AND COMPANY IDENTIFICATION

IDH number:

Product name: LOCTITE® 4601™ INSTANT

ADHESIVE PRISM® MEDICAL DEVICE

ADHESIVE

Product type:CyanoacrylateItem number:18692Restriction of Use:None identifiedRegion:United States

Company address: Contact information:

Henkel Corporation Telephone: +1 (860) 571-5100

One Henkel Way

MEDICAL EMERGENCY Phone: Poison Control Center
Rocky Hill, Connecticut 06067

1-877-671-4608 (toll free) or 1-303-592-1711

TRANSPORT EMERGENCY Phone: CHEMTREC 1-800-424-9300 (toll free) or 1-703-527-3887

229810

Internet: www.henkelna.com

2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

WARNING: BONDS SKIN IN SECONDS.

COMBUSTIBLE LIQUID. CAUSES EYE IRRITATION.

HAZARD CLASS	HAZARD CATEGORY
FLAMMABLE LIQUID	4
EYE IRRITATION	2B

PICTOGRAM(S)	
None	

Precautionary Statements

Prevention:

Keep away from heat, sparks, open flames, hot surfaces - no smoking. Wash affected area

thoroughly after handling. Wear protective gloves, eye protection, and face protection.

Response:

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present

and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. In case of fire:

Use foam, dry chemical or carbon dioxide to extinguish.

Storage:

Store in a well-ventilated place. Keep cool.

Disposal:

Dispose of contents and/or container according to Federal, State/Provincial and local

governmental regulations.

Classification complies with OSHA Hazard Communication Standard (29 CFR 1910.1200) and is consistent with the provisions of the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

See Section 11 for additional toxicological information.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous Component(s)	CAS Number	Percentage*
Beta-Methoxyethyl Cyanoacrylate	27816-23-5	90 - 100

IDH number: 229810 Product name: LOCTITE® 4601™ INSTANT ADHESIVE PRISM® MEDICAL DEVICE ADHESIVE Page 1 of 6

* Exact percentages may vary or are trade secret. Concentration range is provided to assist users in providing appropriate protections.

4. FIRST AID MEASURES

Inhalation: Move to fresh air. If breathing is difficult, give oxygen. If not breathing, give

artificial respiration. If symptoms develop and persist, get medical attention.

Skin contact: Do not pull bonded skin apart. Soak in warm soapy water. Gently peel apart

using a blunt instrument. If skin is burned due to the rapid generation of heat by a large drop, seek medical attention. If lips are bonded, apply warm water to the lips and encourage wetting and pressure from saliva in mouth. Peel or

roll lips apart. Do not pull lips apart with direct opposing force.

Eye contact: Immediately flush with plenty of water for at least 15 minutes. Get medical

attention. If eyelids are bonded closed, release eyelashes with warm water by covering with a wet pad. Do not force eye open. Cyanoacrylate will bond to eye protein and will cause a lachrymatory effect which will help to debond the adhesive. Keep eye covered until debonding is complete, usually within 1-3 days. Medical attention should be sought in case solid particles of polymerized cyanoacrylate trapped behind the eyelid caused abrasive

damage.

Ingestion: Ensure breathing passages are not obstructed. The product will polymerize

rapidly and bond to the mouth making it almost impossible to swallow. Saliva will separate any solidified product in several hours. Prevent the patient from

swallowing any separated mass.

Symptoms: See Section 11.

Notes to physician: Surgery is not necessary to separate accidentally bonded tissues. Experience

has shown that bonded tissues are best treated by passive, non-surgical first

aid. If rapid curing has caused thermal burns they should be treated

symptomatically after adhesive is removed.

5. FIRE FIGHTING MEASURES

Extinguishing media: Water spray (fog), foam, dry chemical or carbon dioxide.

Special firefighting procedures: Wear a self-contained breathing apparatus with a full face piece operated in

pressure-demand or other positive pressure mode.

Unusual fire or explosion hazards: None

IDH number: 229810

Hazardous combustion products: Trace amounts of toxic and/or irritating fumes may be released and the use of

breathing apparatus is recommended.

6. ACCIDENTAL RELEASE MEASURES

Use personal protection recommended in Section 8, isolate the hazard area and deny entry to unnecessary and unprotected personnel.

Environmental precautions: Ventilate area. Do not allow product to enter sewer or waterways.

Clean-up methods: 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. Refer to Section 8 "Exposure Controls / Personal Protection" prior to

clean up.

7. HANDLING AND STORAGE

Handling: Prevent contact with eyes, skin and clothing. Do not breathe vapor and mist.

Wash thoroughly after handling. Avoid contact with fabric or paper goods. Contact with these materials may cause rapid polymerization which can generate smoke and strong irritating vapors, and cause thermal burns.

Storage: Keep in a cool, well ventilated area away from heat, sparks and open flame.

Keep container tightly closed until ready for use.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Employers should complete an assessment of all workplaces to determine the need for, and selection of, proper exposure controls and protective equipment for each task performed.

Hazardous Component(s)	ACGIH TLV	OSHA PEL	AIHA WEEL	OTHER
Beta-Methoxyethyl Cyanoacrylate	None	None	None	0.2 ppm TWA

Engineering controls: Use positive down-draft exhaust ventilation if general ventilation is insufficient

to maintain vapor concentration below established exposure limits.

Respiratory protection: Use NIOSH approved respirator if there is potential to exceed exposure

limit(s).

Eye/face protection: Safety goggles or safety glasses with side shields. Full face protection should

be used if the potential for splashing or spraying of product exists.

Skin protection: Use nitrile gloves and aprons as necessary to prevent contact. Do not use

PVC, nylon or cotton.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid

Color: Clear, Colorless, to, Straw
Odor: Negligible

Odor:NegligibleOdor threshold:Not available.pH:Not applicableVapor pressure:< 0.2 mm hg</th>

Boiling point/range: $> 300 \, ^{\circ}\text{F} \, (> 148.9 \, ^{\circ}\text{C})$

Melting point/ range: Not determined

Specific gravity: 1.1

Vapor density: Not available.

Flash point: 80 - 93 °C (176°F - 199.4 °F)

Flammable/Explosive limits - lower:

Flammable/Explosive limits - upper:

Autoignition temperature:

Flammability:

Flammability:

Evaporation rate:

Not determined
Not applicable
Not available.

Solubility in water: Polymerises in presence of water.

Partition coefficient (n-octanol/water): Not applicable

VOC content: < 2 %; < 20 g/l (California SCAQMD Method 316B) (Estimated)

Viscosity:Not available.Decomposition temperature:Not available.

IDH number: 229810

10. STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.

Hazardous reactions: Rapid exothermic polymerization will occur in the presence of water, amines, alkalis and

alcohols.

Hazardous decomposition

products:

IDH number: 229810

None

Incompatible materials: Water, amines, alkalis and alcohols.

Reactivity: Not available.

Conditions to avoid: Spontaneous polymerization.

11. TOXICOLOGICAL INFORMATION

Relevant routes of exposure: Skin, Inhalation, Eyes

Potential Health Effects/Symptoms

Inhalation: May cause respiratory tract irritation. Exposure to vapors above the established exposure limit

results in respiratory irritation, which may lead to difficulty in breathing and tightness in the

chest.

Skin contact: May cause skin irritation. Bonds skin in seconds. Cyanoacrylates have been reported to cause

allergic reaction but due to rapid polymerization at the skin surface, an allergic response is rare. Cyanoacrylates generate heat on solidification. In rare circumstances a large drop will burn the

skin. Cured adhesive does not present a health hazard even if bonded to the skin.

Eye contact: Irritating to eyes. Causes excessive tearing. Eyelids may bond.

Ingestion: Not expected to be harmful by ingestion. Rapidly polymerizes (solidifies) and bonds in mouth. It

is almost impossible to swallow.

Hazardous Component(s)	LD50s and LC50s	Immediate and Delayed Health Effects	
Beta-Methoxyethyl Cyanoacrylate	None	Irritant, Allergen	

Hazardous Component(s)	NTP Carcinogen	IARC Carcinogen	OSHA Carcinogen (Specifically Regulated)
Beta-Methoxyethyl Cyanoacrylate	No	No	No

12. ECOLOGICAL INFORMATION

Ecological information: Not available.

13. DISPOSAL CONSIDERATIONS

Information provided is for unused product only.

Recommended method of disposal: Follow all local, state, federal and provincial regulations for disposal.

Hazardous waste number: Not a RCRA hazardous waste.

14. TRANSPORT INFORMATION

The transport information provided in this section only applies to the material/formulation itself, and is not specific to any package/configuration.

U.S. Department of Transportation Ground (49 CFR)

Proper shipping name: Combustible liquid, n.o.s. (Cyanoacrylate ester)

Hazard class or division: Combustible Liquid

Identification number: NA 1993 Packing group: Ш

International Air Transportation (ICAO/IATA)

Proper shipping name: Aviation regulated liquid, n.o.s. (Cyanoacrylate ester)

Ш

Hazard class or division: 9 Identification number: UN 3334

Packing group: **Exceptions:** Primary packs containing less than 500ml are unregulated by this mode of

transport and may be shipped unrestricted.

Water Transportation (IMO/IMDG)

Proper shipping name: Not regulated Hazard class or division: None Identification number: None Packing group: None

15. REGULATORY INFORMATION

United States Regulatory Information

TSCA 8 (b) Inventory Status: All components are listed or are exempt from listing on the Toxic Substances Control Act

Inventory.

TSCA 12 (b) Export Notification: None above reporting de minimis

CERCLA/SARA Section 302 EHS: None above reporting de minimis. CERCLA/SARA Section 311/312: Reactive, Fire, Immediate Health

This product contains the following toxic chemicals subject to the reporting requirements of CERCLA/SARA Section 313:

section 313 of the Emergency Planning and Community Right-To-Know Act of 1986 (40

CFR 372). Beta-Methoxyethyl Cyanoacrylate (CAS# 27816-23-5).

California Proposition 65: No California Proposition 65 listed chemicals are known to be present.

Canada Regulatory Information

IDH number: 229810

CEPA DSL/NDSL Status: All components are listed on or are exempt from listing on the Canadian Domestic

Substances List.

16. OTHER INFORMATION

This safety data sheet contains changes from the previous version in sections: New Safety Data Sheet format.

Product name: LOCTITE® 4601™ INSTANT ADHESIVE PRISM® MEDICAL DEVICE ADHESIVE

Prepared by: Product Safety and Regulatory Affairs

Issue date: 05/31/2018

IDH number: 229810

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