



Revision Number: 003.0

Issue date: 08/08/2014

1. PRODUCT AND COMPANY IDENTIFICATION

Product name:	4011 Prism® Medical Device Instant Adhesive	IDH number:	142059
Product type:	Cyanoacrylate	Item number:	18680
Restriction of Use:	None identified	Region:	United States
Company address:	Contact information:		
Henkel Corporation	Telephone: (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		
	Internet: www.henkelna.com		

2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

WARNING: BONDS SKIN IN SECONDS.
 COMBUSTIBLE LIQUID.
 CAUSES EYE IRRITATION.
 MAY CAUSE RESPIRATORY IRRITATION.

HAZARD CLASS	HAZARD CATEGORY
FLAMMABLE LIQUID	4
EYE IRRITATION	2B
SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE	3

PICTOGRAM(S)



Precautionary Statements

Prevention: Keep away from heat, sparks, open flames, hot surfaces - no smoking. Avoid breathing vapors, mist, or spray. Wash thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear protective gloves, eye protection, and face protection.

Response: IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to remove. Continue rinsing. Call a poison control center or physician if you feel unwell. 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 container tightly closed. Store in a well-ventilated place. Keep cool. Store locked up.

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*
Ethyl 2-cyanoacrylate	7085-85-0	60 - 100
Thickener	Proprietary	5 - 10

* Exact percentage is a 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

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.

For information on product shelf life contact Henkel Customer Service at (800) 243-4874.

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
Ethyl 2-cyanoacrylate	0.2 ppm TWA	None	None	None
Thickener	None	None	None	None

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:

Colorless to light yellow

Odor:

Irritating

Odor threshold:

Not available.

pH:

Not applicable

Vapor pressure:

< 0.5 mm hg (77 °F (25°C))

Boiling point/range:

> 149 °C (> 300.2 °F) None

Melting point/ range:

Not determined

Specific gravity:

1.05 at 68 °F (20°C)

Vapor density:

Not available.

Flash point:

80 - 93 °C (176°F - 199.4 °F) Tagliabue closed cup

Flammable/Explosive limits - lower:

Not available.

Flammable/Explosive limits - upper:

Not available.

Autoignition temperature: Not available.
Evaporation rate: Not available.
Solubility in water: Polymerises in presence of water.
Partition coefficient (n-octanol/water): Not applicable
VOC content: < 2.00 %; < 20 g/l (California SCAQMD Method 316B) (Estimated)
Viscosity: Not available.
Decomposition temperature: Not available.

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: 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
Ethyl 2-cyanoacrylate	None	Irritant, Allergen, Respiratory
Thickener	None	Irritant

Hazardous Component(s)	NTP Carcinogen	IARC Carcinogen	OSHA Carcinogen (Specifically Regulated)
Ethyl 2-cyanoacrylate	No	No	No
Thickener	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: III

International Air Transportation (ICAO/IATA)

Proper shipping name: Aviation regulated liquid, n.o.s. (Cyanoacrylate ester)
Hazard class or division: 9
Identification number: UN 3334
Packing group: III
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: Immediate Health, Delayed Health, Fire, Reactive
CERCLA/SARA Section 313: None above reporting de minimis
California Proposition 65: No California Proposition 65 listed chemicals are known to be present.

Canada Regulatory Information

CEPA DSL/NDSL Status: Contains one or more components listed on the Non-Domestic Substances List. All other components are listed on or are exempt from listing on the Domestic Substances List. Components listed on the NDSL must be tracked by all Canadian Importers of Record as required by Environment Canada. They may be imported into Canada in limited quantities. Please contact Regulatory Affairs for additional details.

16. OTHER INFORMATION

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

Prepared by: Catherine Bimler, Regulatory Affairs Specialist
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LOCTITE[®] 4011™

November 2012

PRODUCT DESCRIPTION

LOCTITE[®] 4011™ provides the following product characteristics:

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

LOCTITE[®] 4011™ is designed for the assembly of difficult-to-bond materials which require uniform stress distribution and strong tension and/or shear strength. LOCTITE[®] 4011™ is particularly suited for bonding porous or absorbent materials such as wood, paper, leather and fabric. Suitable for use in the assembly of **disposable medical devices**. The product provides rapid bonding of a wide range of materials, including metals, plastics and elastomers.

ISO-10993

An ISO 10993 Test Protocol is an integral part of the Quality Program for LOCTITE[®] 4011™. LOCTITE[®] 4011™ has been qualified to Henkel's ISO 10993 Protocol as a means to assist in the selection of products for use in the medical device industry. Certificates of Compliance are available on Henkel's website or through the Henkel Quality Department.

TYPICAL PROPERTIES OF UNCURED MATERIAL

Specific Gravity @ 25 °C	1.06
Flash Point - See SDS	
Viscosity, Cone & Plate, mPa·s (cP):	
Temperature: 25 °C, Shear Rate: 3,000 s ⁻¹	70 to 110
Viscosity, Brookfield - LVF, 25 °C, mPa·s (cP):	
Spindle 1, speed 30 rpm,	90 to 140 ^{LMS}

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 °C / 50 % relative humidity. This is defined as the time to develop a shear strength of 0.1 N/mm².

Fixture Time, seconds:

Steel	20 to 45
Aluminum	2 to 10
Zinc dichromate	10 to 30
Neoprene	<5
Rubber, nitrile	<5
ABS	1 to 2
PVC	3 to 10
Polycarbonate	5 to 10
Phenolic	<2
Wood (balsa)	<1
Wood (oak)	10 to 30
Wood (pine)	10 to 20
Chipboard	5 to 10
Fabric	10 to 20
Leather	5 to 10
Paper	5 to 10

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. Higher relative humidity levels result in more rapid speed of cure.

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

Cured for 1 week @ 22 °C

Physical Properties:

Coefficient of Thermal Expansion, ISO 11359-2, K ⁻¹	107×10 ⁻⁶
Coefficient of Thermal Conductivity, ISO 8302, W/(m·K)	0.4
Glass Transition Temperature ISO 11359-2, °C	121

Electrical Properties:

Volume Resistivity, IEC 60093, Ω·cm	277×10 ¹⁵
Surface Resistivity, IEC 60093, Ω	69×10 ¹⁵

Dielectric Breakdown Strength, IEC 60243-1, kV/mm 33
 Dielectric Constant / Dissipation Factor, IEC 60250:
 1 kHz 2.72 / 0.02
 1 MHz 2.53 / 0.02
 10 MHz 2.42 / 0.01

TYPICAL PERFORMANCE OF CURED MATERIAL

Adhesive Properties

Cured for 10 seconds @ 25 °C

Tensile Strength, ISO 6922:
 Buna-N N/mm² ≥6.9^{LMS}
 (psi) (≥1,000)

Cured for 72 hours @ 22 °C

Tensile Strength, ISO 6922:
 Buna-N N/mm² 8 to 15
 (psi) (1,200 to 2,200)
 Steel (grit blasted) N/mm² 7 to 16
 (psi) (1,000 to 2,300)

Lap Shear Strength, ISO 4587:

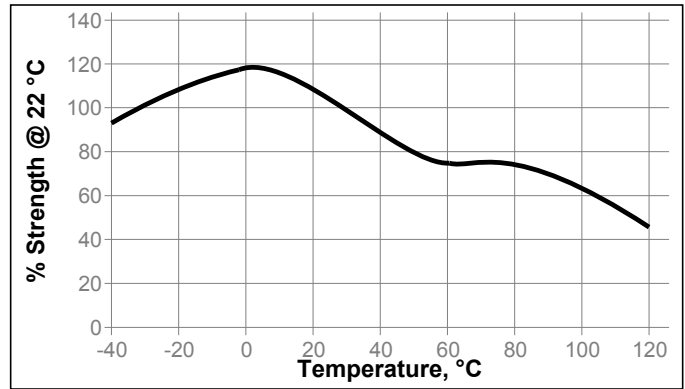
Steel (grit blasted) N/mm² 17 to 24
 (psi) (2,500 to 3,500)
 Aluminum (etched) N/mm² 2 to 11
 (psi) (290 to 1,600)
 Zinc dichromate N/mm² 0.5 to 2
 (psi) (70 to 290)
 ABS N/mm² 7 to 9
 (psi) (1,000 to 1,300)
 PVC N/mm² 7 to 16
 (psi) (1,000 to 2,300)
 Phenolic N/mm² 1 to 5
 (psi) (150 to 730)
 Polycarbonate N/mm² 7 to 11
 (psi) (1,000 to 1,600)
 Nitrile N/mm² 1 to 2
 (psi) (150 to 290)
 Neoprene N/mm² 1 to 2
 (psi) (150 to 290)

TYPICAL ENVIRONMENTAL RESISTANCE

Cured for 1 week @ 22 °C
 Lap Shear Strength, ISO 4587:
 Steel (grit blasted)

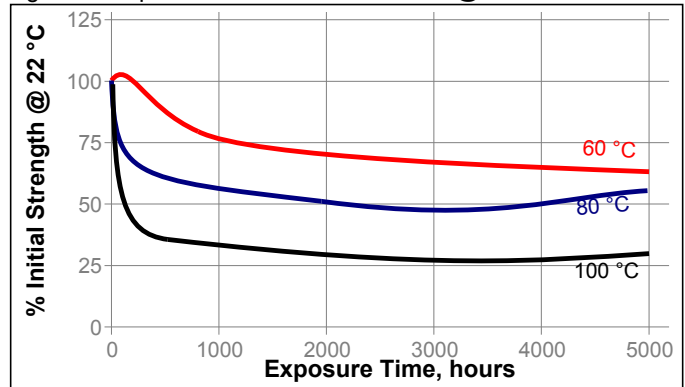
Hot Strength

Tested at temperature



Heat Aging

Aged at temperature indicated and tested @ 22 °C



Chemical/Solvent Resistance

Aged under conditions indicated and tested @ 22 °C.

Environment	°C	% of initial strength			
		100 h	500 h	1000 h	5000 h
Motor oil	40	120	110	110	85
Unleaded gasoline	22	85	80	80	75
Ethanol	22	100	105	110	120
Isopropanol	22	100	110	105	120
Water	22	80	70	55	65
98% RH	40	70	60	55	55

Lap Shear Strength, ISO 4587:
 Polycarbonate

Environment	°C	% of initial strength			
		100 h	500 h	1000 h	5000 h
Air	22	120	125	115	130
98% RH	40	120	110	120	115

Effects of Sterilization

In general, products similar in composition to LOCTITE® 4011™ subjected to standard sterilization methods, such as EtO and Gamma Radiation (25 to 50 kiloGrays cumulative) show excellent bond strength retention. LOCTITE® 4011™ 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:

1. 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.

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 Technical Service Center or Customer Service Representative.

Loctite Material Specification^{LMS}

LMS dated December 29, 2009. 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.

Conversions

$(^{\circ}\text{C} \times 1.8) + 32 = ^{\circ}\text{F}$
 $\text{kV/mm} \times 25.4 = \text{V/mil}$
 $\text{mm} / 25.4 = \text{inches}$
 $\mu\text{m} / 25.4 = \text{mil}$
 $\text{N} \times 0.225 = \text{lb}$
 $\text{N/mm} \times 5.71 = \text{lb/in}$
 $\text{N/mm}^2 \times 145 = \text{psi}$
 $\text{MPa} \times 145 = \text{psi}$
 $\text{N}\cdot\text{m} \times 8.851 = \text{lb}\cdot\text{in}$
 $\text{N}\cdot\text{m} \times 0.738 = \text{lb}\cdot\text{ft}$
 $\text{N}\cdot\text{mm} \times 0.142 = \text{oz}\cdot\text{in}$
 $\text{mPa}\cdot\text{s} = \text{cP}$

Note:

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.

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Reference 1.3