SAFETY DATA SHEETS

This SDS packet was issued with item:

071705284

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

071017052 071704550 078273178

HEALTH Dentsply Caulk HAZARD Manufacturer MSDS Number: NFPA Deadly 3 **■ Extreme DANGER** 0 0 Hazardous Slighty Hazardous Normal Material PERSONAL PROTECTION ☐ Mask Patterson Dental Supply Product Code: ☐ Eye Protection 71705201,71705037,71705284,71705029,71705011,71705003 ☐ Gloves ☐ Barrier Garment Other. **************** SmartPractice (800)522-0800 SECTION 1 : Chemical Product and Company Identification ****************** MSDS Name: Calibra Silane Coupling Agent Manufacturer Name: Dentsply Caulk Department: Dentsply Caulk Address: 38 West. Clarke Avenue Milford DE 19963-0359 Internet Address: http://www.caulk.com Business Phone: (302) 422-4511 For information in North America, call: (302) 422-4511 For emergencies in the US, call CHEMTREC: 800-424-9300 Hours Of Operation: (8:00 AM û 4:30 PM Eastern Time) Manufacturer MSDS Revision Date: 02/19/02 Supersedes: 3/4/99 Trade Names: CALIBRA TM Silane Coupling Agent NFPA Health: 0 Flammability: 3 Reactivity: 0 Other: NFPA HAZARD CLASSIFICATIONS: Specific Hazard: Not Applicable Product Codes: 607060 û 607080 All Package Configurations ******************* SECTION 2 : Hazardous Ingredients/Identity Information ****************** Chemical Name Ethyl Alcohol CAS# 64-17-5 Percent 92.6% OSHA PEL TWA: 1000 ppm ACGIH TLV TWA: 1000 ppm Hazardous: Yes

MSDS Number

FIRE HAZARI

Flash Points

Above 100° F, No

Exceeding 200°

REACTIVITY

May Detonate

☐ Violent Chemical

Unstable if Heate

Change

■ May Detonate Shock and Heat

Below 73° F

■ Below-100° F

■ Above 200° F

■ Will Not Burn

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Chemical Name
Acetone CAS#
67-64-1 Percent
7.4%
OSHA PEL TWA: 500 ppm
ACGIH TLV TWA: 500 ppm
Hazardous: Yes
Chemical Name
Benzene CAS#
71-43-2 Percent
< than 0.15 ppm
OSHA PEL TWA: 0.5 ppm
ACGIH TLV TWA: 0.5 ppm
Hazardous: Yes
*******************
SECTION 3 : Physical And Chemical Characteristics
******************
Physical State/Appearance:
 Clear liquid
Odor:
 Characteristic alcohol odor.
Vapor Pressure:
 44.6
Vapor Density:
 1.59
Boiling Point:
 78 deg C (173 deg F)
Melting Point:
-114 deg C (-173 deg F)
Solubility:
 In water: Completely Soluble.
Specific Gravity:
0.8 \text{ g/cm}^2
Evaporation Point:
Not Established.
FlashPoint:
6 deg C (43 deg F)
Auto Ignition Temp:
423 deg C (793 deg F)
Upper Flammable Explosive Limit:
Lower Flammable Explosive Limit:
3.3
************************
SECTION 4 : Fire And Explosion Hazards
**********************
Flash Point:
6 deg C (43 deg F)
Flash Point Method:
Tag Closed Cup
Upper Flammable or Explosive Limit: 19
Lower Flammable or Explosive Limit: 3.3
Auto Ignition Temperature: 423 deg C (793 deg F)
Extinguishing Media:
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Use dry chemical, alcohol foam, or carbon dioxide. Water may be ineffective, but should be used to keep fire-exposed containers cool. Hazardous Combustion Byproducts:

Incomplete combustion may produce carbon monoxide and/or carbon dioxide.

Fire Fighting Instructions:

If a leak or spill has not ignited, use water spray to disperse vapors and protect personnel attempting to stop a leak. Water spray may be used to flush spills away from exposures and to dilute spills to nonflammable mixtures.

Unusual Fire Hazards:

Firefighters should wear full protective clothing including a self-contained breathing apparatus in the positive pressure mode with a full facepiece when there is a possibility of exposure to smoke, fumes or hazardous decomposition products.

SECTION 5 : Health Hazards

Applies to All Ingredients:

Route of Exposure:

Inhalation: Possible

Skin: Yes

Ingestion: Possible

Potential Health Effects:

Summary of Acute Hazards: Minimal health hazard in normal use and in the quantities present in this product.

For larger quantities and with prolonged exposure, ethyl alcohol is considered a moderate health hazard.

Chronic Health Effects:

Summary of Chronic Hazards: Not a chronic hazard under the normal conditions of use. However, if ingested in large quantities for a prolonged period of time, may be a carcinogenic or a cause of Fetal Alcohol syndrome.

Carcinogenicity:

Not a carcinogen under normal conditions of use.

The IARC has reported a relationship between prolonged drinking of significant quantities of alcoholic beverages and cancer of the oral cavity, pharynx, esophagus and liver.

OSHA Designation: Regulated: No

NTP Designation: Not listed

IARC Designation: Monographs: Not listed

Reproductive Toxin Information:

Ingestion of alcohol by pregnant women is associated with Fetal Reproductive Toxicity.

Signs/Symptoms:

Inhalation: None in normal conditions of use. Exposure to over 1000 ppm may cause headache, drowsiness and lassitude, loss of appetite, inability to concentrate, and irritation of throat.

Eye Contact: Liquid or vapor may cause irritation.

Skin Absorption: None in normal conditions of use. However, for large quantities and prolonged contact, similar symptoms to inhalation/ingestion may occur.

Skin Contact: May cause irritation and defatting of skin on prolonged

Ingestion: None in small quantities of normal conditions of use. For large quantities, may cause depression of the central nervous system, nausea, vomiting, diarrhea.

All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA)

Chemical Substance Inventory.

Eye Contact:

In case of eye contact, flush immediately with flowing water for at least 15 minutes. Get prompt medical attention. Skin Contact:

Immediately flush affected area with plenty of cool water. Wash skin with soap and water. If irritation persists, call physician. Ingestion:

For large quantities: If victim is conscious and able to swallow, have victim drink water or milk to dilute. Never give anything by mouth to an unconscious or convulsing person. Call a physician or Poison Control Center immediately. Induce vomiting only on their advice.

Chemical Stability:

Stable

Conditions to Avoid:

(Stability): Heat, flame, sparks, elevated temperatures above 50 deg C (122 deg F).

Incompatibilities with Other Materials:

(Materials to avoid): Avoid acetyl chloride and strong oxidizing materials, which may react violently.

Hazardous Decomposition Products:

Incomplete combustion may produce carbon monoxide or carbon dioxide.

Spill Cleanup Measures:

For small quantities (as in this product): Wear gloves and safety glasses. Pick up with absorbent material, such as paper or cloth. Rinse area of spill with water. Place all material in closed container away from heat, sparks, sun and oxidizers.

Handling:

For small quantities (as in this product): Keep tightly closed, in a well ventilated area, away from heat, sparks, direct sunlight, and oxidizing agents. Protect container against physical damage. Take these same precautions when container is empty, as residual product is hazardous. Storage:

Store away from food and beverages. Store away from extreme heat. Hygiene Practices:

Observe normal care when working with chemicals. Wash hands after use.

Other precautions:

Avoid contact with skin. Observe normal warehouse handling procedures. Handling of this product should be by trained dental healthcare professionals only.

Waste Disposal:

Dispose of in accordance with Federal, State and Local environmental control regulations.

SECTION 9 : Control Measures

Ventilation System:

None required during normal intended use of this product. However for large quantities and prolonged exposure, methods such as enclosure, local ventilation and dilution are recommended to reduce concentration below TLV.

Hand Protection Description:

Protective gloves: Chemically impervious gloves are recommended when skin contact is possible.

Eye/Face Protection:

Safety glasses are recommended when no eye contact is anticipated. Chemical safety goggles should be worn whenever there is a possibility of splashing or other contact with eyes.

Protective Clothing/Body Protection:

Chemically resistant apron or other impervious clothing.

Respiratory Protection:

None required during normal use of this product.

Work/Hygienic practices:

Observe normal care when working with chemicals. Wash hands after use. Avoid eye and skin contact, inhalation and ingestion. Do not eat, drink or smoke when using.

SECTION 10 : Other Information

Applies to all ingredients: TSCA 8(b): Inventory Status

All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.

NFPA:

Fire Hazard: 3
Health: 0
Reactivity: 0

Specific Hazard: Not Applicable

MSDS Revision Date:

02/19/02

Supersedes: 3/4/99

Abbreviations:

NFPA û National Fire Protection Association

N.A. - Not Applicable N.E. - Not Established

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Printing date 19.03.2015 Version number 5 Revision: 19.03.2015

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

- · 1.1 Product identifier
- · Trade name: Calibra Silane Coupling Agent
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against
- · Application of the substance / the mixture Silane Coupling Agent
- · Uses advised against No further relevant information available.
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

DENTSPLY DeTrey GmbH

De-Trey-Str. 1 D-78467 Konstanz GERMANY

Tel.: +49-(0)7531-583-0 *Fax*: +49-(0)7531-583-104

email: KonstanzDEU.info-sdb@dentsply.com

- · Further information obtainable from:
- Departement Analytical Research / Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets
- 1.4 Emergency telephone number: +49-(0)7531-583-0 8:00 17:00 (GMT + 1:00)

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation 1272/2008.

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms



- · Signal word Danger
- · Hazard statements

H225 Highly flammable liquid and vapour.

· Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No

smoking.

P241 Use explosion-proof electrical/ventilating/lighting/equipment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with

water/shower.

P403+P235 Store in a well-ventilated place. Keep cool.

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

regulations.

- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable. · **vPvB**: Not applicable.

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Trade name: Calibra Silane Coupling Agent

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SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:		
		50-100%
EINECS: 200-578-6	🊸 Flam. Liq. 2, H225	
		2.5-10%
EINECS: 200-662-2	🊸 Flam. Liq. 2, H225; ∿ Eye Irrit. 2, H319; STOT SE 3, H336	

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

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · After inhalation Supply fresh air; consult doctor in case of complaints.
- · After skin contact Immediately wash with water and soap and rinse thoroughly.
- · After eye contact Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing Rinse out mouth and then drink plenty of water.
- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- · For safety reasons unsuitable extinguishing agents Water with full jet.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: Self-contained respiratory protective device.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation

Wear protective equipment. Keep unprotected persons away.

· 6.2 Environmental precautions:

Dilute with plenty of water.

Do not allow to enter sewers/surface or ground water.

 \cdot 6.3 Methods and material for containment and cleaning up:

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

· 6.4 Reference to other sections

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling Observe normal care for working with chemicals.
- · Handling Product is intended for dental use only.

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· Information about fire - and explosion protection:

(Contd. of page 2)



Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage
- · Requirements to be met by storerooms and receptacles: Store in a cool location.
- · Information about storage in one common storage facility: Store away from oxidising agents.
- · Further information about storage conditions: Store in cool, dry conditions in well sealed receptacles.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters

· Ingredients with limit values that require monitoring at the workplace:	
64-17-5 ethanol	

WEL Long-term value: 1920 mg/m³, 1000 ppm

67-64-1 acetone

WEL Short-term value: 3620 mg/m³, 1500 ppm Long-term value: 1210 mg/m³, 500 ppm

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment
- · General protective and hygienic measures Wash hands before breaks and at the end of work.
- · Respiratory protection: Not necessary if room is well-ventilated.
- · Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/the preparation/the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

Butyl rubber, BR

Recommended thickness of the material: ≥ 0.7 mm

Permeation: Level ≥6

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.

· 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.

· Eye protection:



Tightly sealed goggles.

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Trade name: Calibra Silane Coupling Agent

· Body protection: Protective work clothing.

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SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Liquid
Colour: Clear

Odour: Alcohol-like
Odour threshold: Not determined.

pH-value: Not determined.

· Change in condition

Melting point/Melting range: undetermined *Boiling point/Boiling range:* 78 °C

• Flash point: $6 \, ^{\circ}C \, (c.c. \, Abel)$

· Flammability (solid, gaseous) Not applicable.

· Ignition temperature: 425 °C

· Decomposition temperature: Not determined.

· Self-igniting: Product is not selfigniting.

• Danger of explosion: Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

· Explosion limits:

 Lower:
 3.5 Vol %

 Upper:
 15.0 Vol %

· Vapour pressure at 20 °C: 59 hPa

Density at 20 °C: 0.8 g/cm³
 Relative density Not determined.
 Vapour density Not determined.
 Evaporation rate Not determined.

· Solubility in / Miscibility with

Water: Partly miscible

- · Partition coefficient (n-octanol/water): Not determined.
- Viscosity:

dynamic: Not determined. kinematic: Not determined.

· Solvent content:

Organic solvents: 98.0 %

• 9.2 Other information No further relevant information available.

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known
- · 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.

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Trade name: Calibra Silane Coupling Agent

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· 10.6 Hazardous decomposition products: No dangerous decomposition products known

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity:

· LD/LC50 values relevant for classification:	
ATE (Acute Toxicity Estimates)	
Inhalative LC50/4 h 95.7 mg/l	

 64-17-5 ethanol

 Oral
 LD50
 6200 mg/kg (rat)

 Inhalative
 LC50/4 h
 95.6 mg/l (rat)

67-64-1 acetone

 Oral
 LD50
 5800 mg/kg (rat)

 Dermal
 LD50
 20000 mg/kg (rabbit)

 Inhalative
 LC50/4 h
 76 mg/l (rat)

- · Primary irritant effect:
- · on the skin: No irritant effect.
- · on the eye: No irritating effect.
- · Sensitisation: No sensitising effects known.

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic to.	· Aquatic toxicity:			
64-17-5 eti	64-17-5 ethanol			
EC50/48h	9268 mg/L (daphnia magna)			
LC50/48h	8140 mg/l (Fish acute toxicity study)			
67-64-1 ac	67-64-1 acetone			
EC50/48h	6100 mg/L (daphnia magna)			
LC50/96h	5540 mg/l (Fish acute toxicity study)			

- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

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

- · 12.5 Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.
- $\cdot \textbf{12.6 Other adverse effects} \ \textit{No further relevant information available}.$

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SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation



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

· European waste catalogue

18 01 06* chemicals consisting of or containing dangerous substances

- · Uncleaned packaging:
- \cdot **Recommendation:** Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

	tion
· 14.1 UN-Number · ADR, IMDG, IATA	UN1993
· 14.2 UN proper shipping name	
$\cdot ADR$	1993 FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETH
· IMDG	ALCOHOL), ACETONE) FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHALOHOL), ACETONE)
· IATA	FLAMMABLE LIQUID, N.O.S. (ETHANOL, ACETONE
· 14.3 Transport hazard class(es)	
· ADR	
· Class	3 (F1) Flammable liquids.
· Cuss · Label	3 (F1) Flammable liquias. 3
· IMDG, IATA	
· Class	3 Flammable liquids.
· Label	3
· 14.4 Packing group	
· ADR, IMDG, IATA	II
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Warning: Flammable liquids.
· Danger code (Kemler):	33 F F G F
· EMS Number:	F-E, <u>S-E</u>
· 14.7 Transport in bulk according to Ann	nex II of

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Trade name: Calibra Silane Coupling Agent

	(Contd. of page
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	IL
· Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
· Transport category	2
· Tunnel restriction code	D/E
· IMDG	
· Limited quantities (LQ)	IL
· Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN1993, FLAMMABLE LIQUID, N.O.S. (ETHANO.
-	(ETHYL ALCOHOL), ACETONE), 3, II

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · National regulations
- · Information about limitation of use: Employment restrictions concerning juveniles must be observed.
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

· Relevant phrases

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

- · Department issuing MSDS: Analytical Research
- · Contact: HotLine for urgent technical support: +49-7531-583-350
- · 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)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Flam. Liq. 2: Flammable liquids, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

* Data compared to the previous version altered.

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