# **SAFETY DATA SHEETS**

# This SDS packet was issued with item: 070447433

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

070446948 070447177 071803352 071803360 071803626 071805324 071805332

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).

070446955 071704550 071837202



Moisture-Activated Temporary Filling and Sealling Material

#### **SECTION I - PRODUCT / COMPANY IDENTIFICATION**

Product Name: TEMPIT® TEMPORARY FILLING MATERIAL Synonyms: Temporary filling material Part (Item) Number: 310060, 360053 Company Name: Centrix, Inc. Address: 770 River Road City, State, Zip: Shelton CT, 06484 Emergency Telephone Number: 203-929-5582 Information Telephone Number: 800-235-5862

## SECTION II - COMPOSITION / INFORMATION ON INGREDIENTS

	/				
Hazardous Components:	%	CAS No.	SYMBOL	R	EINECS No.
D.M.T.G (Glycol)	<12%	143-24-8			205-594-7
Ethyl Methacrylate Polymer	<3%				
Calcium Sulphate	<59%	10034-76-1			231-900-3
Zinc Oxide	<11%	1314-13-2			
Barium Sulphate	<17%	7727-43-7			
Silica (Amorphous)	<2%	7631-86-9			231-545-4

#### SECTION III - HAZARDS IDENTIFICATION

For potential health hazards: See section 11 below. No other significant hazards to man or the environment are reasonably foreseen.

# **SECTION IV - FIRST AID MEASURES**

Skin: Wash with soap and water. Eyes: Flush with copious amounts of water. If irritation persists, seek medical attention. Ingestion: N/A Inhalation: N/A

#### SECTION V - FIRE-FIGHTING MEASURES

Use extinguisher suitable to cause of fire and its surroundings. Suitable extinguishing media: N/A Special firefighting measures: N/A Special protection equipment: N/A

#### SECTION VI - ACCIDENTAL RELEASE MEASURES

Transfer bulk into suitable containers for disposal. Wipe residue with damp cloth and scrape up into suitable container for disposal. Personal precautions: N/A Environmental precautions: N/A Reclaiming methods: N/A

#### **SECTION VII - HANDLING AND STORAGE**

Handling: No handling problems are likely to be encountered provided normal safe practices of hygiene are applied.Storage: Store in a cool dry place.Containers: N/AIncompatibilities: N/AOther precautions: N/A

#### **SECTION VIII - EXPOSURE CONTROLS / PERSONAL PROTECTION**

General measures: Wash hands thoroughly after contact with this product. Limits: N/A Respiratory protection: N/A Eye protection: Goggles/eyeshields. Skin protection: Overalls, rubber gloves. Hands protection: Overalls, rubber gloves. Other equipment: N/A

# SECTION IX - PHYSICAL AND CHEMICAL PROPERTIES

Appearance: White stiff paste Odor: Odorless Explosion limits: N/A Water solubility: Insoluble Boiling point: N/A Evaporation rate: N/A Flash point: N/A

# SECTION X - STABILITY AND REACTIVITY

Stability: Stable, non-reactive Conditions to avoid: N/A Materials to avoid: N/A Hazardous decomposition products: N/A Hazardous polymerization products: N/A

# SECTION XI - TOXICOLOGICAL INFORMATION

Ingestion: N/A Eye contact: N/A Skin contact: N/A Inhalation: N/A Prolonged exposure: N/A

# SECTION XII - ECOLOGICAL INFORMATION

#### **SECTION XIII - DISPOSAL CONSIDERATIONS**

Dispose of in accordance with all federal, state, and local regulations.

## SECTION XIV - TRANSPORT INFORMATION

#### SECTION XV - REGULATORY INFORMATION

Product covered by one or more of the following patents: US 4,963,093 and US

D353673. Other U.S. and International patents pending or granted.

Hazard Classification Symbol: N/A Ingredients determining the label: The information is this MSDS does not constitute an assessment of workplace risk.

#### SECTION XVI - OTHER INFORMATION

Handling of product exclusively by dental specialists according to instructions for use.

#### CAUTION: PRODUCT FOR PROFESSIONAL USE ONLY

The above information is based on presently available data and to our best knowledge for handling the product under normal conditions. Any use of this product in any way not indicated on this document or using it together with any other process/procedure will be exclusively under the user's responsibility.



Making Dentistry Easier.™

0510

770 River Road, Shelton, CT 06484 USA (800) 235-5862 Tel: (203) 929-5582 Fax: (203) 929-6804

**CENTRIX INCORPORATED** 

EC

**CENTRIX EUROPE** 

Hauptstrasse 64 B, 65719 Hofheim, Germany

©Centrix, Inc. 2006 Date Revised 10/15/2010

Obtained by Global Safety Management, Inc. www.globalsafetynet.com; Tel: 1-813-435-5161





Printing date 14.02.2017

Version number 7

Revision: 14.02.2017

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

· 1.1 Product identifier

· Trade name: Prime & Bond NT

- · 1.2 Relevant identified uses of the substance or mixture and uses advised against
- · Application of the substance / the mixture Adhesive
- · Uses advised against No further relevant information available.
- $\cdot$  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@dentsplysirona.com

· Further information obtainable from:

- Departement 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.
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
STOT SE 3 H336 May cause drowsiness or dizziness.
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

#### · 2.2 Label elements

- · Labelling according to Regulation (EC) No 1272/2008
- *The product is classified and labelled according to the CLP regulation. Hazard pictograms*



· Signal word Danger

· Hazard-determining components of labelling: acetone *Di(ethylene glycol) dimethacrylate* · Hazard statements H225 Highly flammable liquid and vapour. H315 Causes skin irritation. H319 Causes serious eye irritation. H317 May cause an allergic skin reaction. H336 May cause drowsiness or dizziness. H412 Harmful to aquatic life with long lasting effects. · 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.

(Contd. on page 2)

Printing date 14.02.2017

Version number 7

Revision: 14.02.2017

Trade name: Prime & Bond NT

	(Contd. of page 1)
P303+P361	+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P305+P351	+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
· Additional i	nformation:

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.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

· **PBT:** Not applicable.

• **vPvB:** Not applicable.

#### **SECTION 3: Composition/information on ingredients**

· 3.2 Chemical characterisation: Mixtures

• Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous compone	ents:	
CAS: 67-64-1	acetone	50-100%
EINECS: 200-662-2	🚸 Flam. Liq. 2, H225; 🚸 Eye Irrit. 2, H319; STOT SE 3, H336	
CAS: 105883-40-7	Urethane Dimethacrylate Resin	10-25%
	🚸 Skin Irrit. 2, H315; Eye Irrit. 2, H319	
CAS: 87699-25-0	Dipentaerythritol pentaacrylate phosphate	2.5-<10%
	Aquatic Chronic 2, H411;  Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 2358-84-1	Di(ethylene glycol) dimethacrylate	2.5-<10%
	� Skin Sens. 1, H317	
CAS: 3290-92-4	propylidynetrimethyl trimethacrylate	0.25-<2.5%
	Aquatic Chronic 2, H411	
CAS: 128-37-0	2,6-di-tert-butyl-p-cresol	0.25-<2.5%
EINECS: 204-881-4	log Aquatic Acute 1, H400; Aquatic Chronic 1, H410	
· Additional informat	ion For the wording of the listed hazard phrases refer to section 16.	

#### **SECTION 4: First aid measures**

• 4.1 Description of first aid measures

- · General information Immediately remove any clothing soiled by the product.
- · 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. If symptoms persist, consult a doctor.
- After swallowing If symptoms persist consult doctor.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Information for doctor No further relevant information available.

· 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

(Contd. on page 3)

GB

Printing date 14.02.2017

Version number 7

Revision: 14.02.2017

Trade name: Prime & Bond NT

(Contd. of page 2)

#### **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 Wear protective equipment. Keep unprotected persons away.
 6.2 Environmental precautions:

Inform respective authorities in case of seepage into water course or sewage system. Dilute with plenty of water.

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

· 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. Prevent formation of aerosols. Ensure good ventilation/exhaustion at the workplace.

- · Handling Product is intended for dental use only.
- · Information about fire and explosion protection:



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.
- Store only in the original receptacle.
- · 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.

(Contd. on page 4)

Printing date 14.02.2017

Version number 7

Revision: 14.02.2017

(Contd. of page 3)

Trade name: Prime & Bond NT

· Ingredients with limit values that require monitoring at the workplace:

#### CAS: 67-64-1 acetone

· 8.1 Control parameters

WEL Short-term value: 3620 mg/m<sup>3</sup>, 1500 ppm

Long-term value: 1210 mg/m<sup>3</sup>, 500 ppm

· Regulatory information WEL: EH40/2011

 $\cdot$  DNELs

CAS: 128-37-0 2,6-di-tert-butyl-p-cresol

Inhalative DNEL Werte 3.5 mg/m<sup>3</sup> bw/day (rat)

• Additional information: The lists valid during the making were used as basis.

#### · 8.2 Exposure controls

· Personal protective equipment

• General protective and hygienic measures Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin.

• Respiratory protection:

Not necessary if room is well-ventilated. In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· Protection of hands:



Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

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.

Natural rubber, NR

Recommended thickness of the material:  $\geq 0.75$  mm Permeation: Level  $\geq 2$ 

 $\cdot$  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.

· Body protection: Protective work clothing.

#### **SECTION 9: Physical and chemical properties**

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

Fluid

(Contd. on page 5)

Printing date 14.02.2017

Version number 7

Revision: 14.02.2017

Trade name: Prime & Bond NT

	(Contd. of page 4
Colour:	Yellow
· Odour:	Characteristic
· Odour threshold:	Not determined.
· pH-value:	Not determined.
• Change in condition Melting point/freezing point: Initial boiling point and boiling range	undetermined e: 60 °C
· Flash point:	-19 °C (c.c. Abel)
· Flammability (solid, gaseous)	Not applicable.
· Ignition temperature:	465 °C
Decomposition temperature:	Not determined.
• Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. However, formation of explosive air, vapour mixtures are possible.
· Explosion limits:	
Lower:	2.6 Vol %
Upper:	12.8 Vol %
• Vapour pressure at 20 •C:	233 hPa
· Density at 20 °C:	0.9 g/cm <sup>3</sup>
· 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:	67.0 %
Solids content:	3.0 %
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.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known

#### **SECTION 11: Toxicological information**

· 11.1 Information on toxicological effects

• Acute toxicity Based on available data, the classification criteria are not met.

(Contd. on page 6) GB

Printing date 14.02.2017

Version number 7

Revision: 14.02.2017

Trade name: Prime & Bond NT

LD/LC50			
CAS: 67-6			
Oral	LD50	5800 mg/kg (rat)	
Dermal	LD50	20000 mg/kg (rabbit)	
Inhalative		76 mg/l (rat)	
		lidynetrimethyl trimethacrylate	
Oral	LD50	>2000 mg/kg (rat)	
		tert-butyl-p-cresol	
Oral	LD50	2930 mg/kg (rat)	
Dermal	LD50 LD50	> 2000 mg/kg (rabbit)	
Primary ir			
Skin corro			
	n irritation		
Serious ey	e damage/i	ritation	
	rious eye ir		
Respirator			
Repeated methacryld		ea contact with the not polymerized pro	oduct may cause sensitization for acrylate
		skin reaction.	
		genity, mutagenicity and toxicity for repr	oduction)
		y Based on available data, the classificat	
		l on available data, the classification crite	
		Based on available data, the classification	n criteria are not met.
STOT-sing	gle exposui		
•		or dizziness.	
STOT-rep	eated expo	or dizziness. u <b>re</b> Based on available data, the classific	
STOT-rep Aspiration	eated expo hazard Ba	or dizziness.	
STOT-rep Aspiration	eated expo hazard Ba N 12: Ec	or dizziness. u <b>re</b> Based on available data, the classific red on available data, the classification c	
STOT-rep Aspiration SECTIO	eated expo hazard Ba N 12: Ec	or dizziness. u <b>re</b> Based on available data, the classific red on available data, the classification c	
STOT-rep Aspiration SECTIO 12.1 Toxic	eated expo hazard Bc N 12: Ec ity xicity:	or dizziness. u <b>re</b> Based on available data, the classific eed on available data, the classification co plogical information	
STOT-rep Aspiration SECTIO 12.1 Toxic Aquatic to CAS: 67-6	eated expo hazard Bo N 12: Ec ity xicity: 4-1 aceton	or dizziness. u <b>re</b> Based on available data, the classific eed on available data, the classification co plogical information	
STOT-rep Aspiration SECTIO 12.1 Toxic Aquatic to CAS: 67-6 LC50/96h	eated expo hazard Ba N 12: Ec ity xicity: 4-1 aceton 5540 mg/l	or dizziness. <b>ure</b> Based on available data, the classific red on available data, the classification cr <b>plogical information</b> (Fish acute toxicity study)	
STOT-rep Aspiration SECTIO 12.1 Toxic Aquatic to CAS: 67-6 LC50/96h EC50/48h	eated expo hazard Ba N 12: Ec ity xicity: 4-1 aceton 5540 mg/l 6100 mg/l	or dizziness. <b>ure</b> Based on available data, the classific red on available data, the classification co <b>clogical information</b> (Fish acute toxicity study) (daphnia magna)	
STOT-rep Aspiration SECTIO 12.1 Toxic Aquatic to CAS: 67-6 LC50/96h EC50/48h CAS: 3290	eated expo hazard Ba N 12: Ec ity xicity: 4-1 aceton 5540 mg/l 6100 mg/l <b>9-92-4 prop</b>	or dizziness. <b>ure</b> Based on available data, the classific red on available data, the classification co <b>plogical information</b> Fish acute toxicity study) (daphnia magna) <b>Plidynetrimethyl trimethacrylate</b>	
STOT-rep. Aspiration SECTIO 12.1 Toxic Aquatic to CAS: 67-6 LC50/96h EC50/48h CAS: 3290 LC50/96h	eated expo hazard Ba N 12: Ec ity xicity: 4-1 aceton 5540 mg/l 6100 mg/l <b>2</b> mg/l (Fi	or dizziness. <b>ure</b> Based on available data, the classific red on available data, the classification cr <b>plogical information</b> (Fish acute toxicity study) (daphnia magna) <b>Plidynetrimethyl trimethacrylate</b> h acute toxicity study)	
STOT-rep Aspiration SECTIO 12.1 Toxic Aquatic to CAS: 67-6 LC50/96h EC50/48h CAS: 3290 LC50/96h EC50/48h	eated expo hazard Ba N 12: Ec ity xicity: 5540 mg/l 6100 mg/l 0-92-4 prop 2 mg/l (Fi >9.22 mg/	or dizziness. <b>ure</b> Based on available data, the classific red on available data, the classification co <b>ological information</b> (Fish acute toxicity study) (daphnia magna) <b>bidynetrimethyl trimethacrylate</b> th acute toxicity study) (claphnia magna)	
STOT-rep Aspiration SECTIO 12.1 Toxic Aquatic to CAS: 67-6 LC50/96h EC50/48h CAS: 3290 LC50/96h EC50/48h CAS: 128-	eated expo hazard Ba N 12: Ec ity xicity: 4-1 aceton 5540 mg/l 6100 mg/l 0-92-4 prop 2 mg/l (Fi >9.22 mg/ 37-0 2,6-d	or dizziness. <b>ure</b> Based on available data, the classific red on available data, the classification cr <b>plogical information</b> Fish acute toxicity study) (daphnia magna) <b>plidynetrimethyl trimethacrylate</b> th acute toxicity study) L (daphnia magna) <b>tert-butyl-p-cresol</b>	
STOT-rep Aspiration SECTIO 12.1 Toxic Aquatic to CAS: 67-6 LC50/96h EC50/48h CAS: 3290 LC50/96h EC50/48h CAS: 128- LC50/48h	eated expo hazard Ba N 12: Ec ity xicity: 4-1 aceton 5540 mg/l 6100 mg/l 0-92-4 prop 2 mg/l (Fi >9.22 mg/ 37-0 2,6-di >0.57 mg/	or dizziness. <b>ure</b> Based on available data, the classific red on available data, the classification co <b>ological information</b> (Fish acute toxicity study) (daphnia magna) <b>vlidynetrimethyl trimethacrylate</b> h acute toxicity study) L (daphnia magna) <b>tert-butyl-p-cresol</b> (daphnia magna)	
STOT-rep Aspiration SECTIO 12.1 Toxic Aquatic to CAS: 67-6 LC50/96h EC50/48h CAS: 3290 LC50/96h EC50/48h CAS: 128- LC50/48h LC50/96h	eated expo hazard Ba N 12: Ec ity xicity: 4-1 aceton 5540 mg/l 6100 mg/l 6100 mg/l 9.22 mg/ 2 mg/l (Fi >9.22 mg/ 37-0 2,6-da >0.57 mg/ >0.42 mg/	or dizziness. <b>are</b> Based on available data, the classific red on available data, the classification cr <b>blogical information</b> Fish acute toxicity study) (daphnia magna) <b>bidynetrimethyl trimethacrylate</b> th acute toxicity study) (daphnia magna) <b>tert-butyl-p-cresol</b> (daphnia magna) (Fish acute toxicity study)	
STOT-rep Aspiration SECTIO 12.1 Toxic Aquatic to CAS: 67-6 LC50/96h EC50/48h CAS: 3290 LC50/96h EC50/48h LC50/96h LC50/96h EC50/72h	eated expo hazard Ba N 12: Ec ity xicity: 4-1 aceton 5540 mg/l 6100 mg/l 6100 mg/l 9.22 mg/ 2 mg/l (Fi >9.22 mg/ 37-0 2,6-dt >0.57 mg/ >0.42 mg/ >0.42 mg/	or dizziness. <b>are</b> Based on available data, the classific red on available data, the classification cr <b>plogical information</b> Fish acute toxicity study) (daphnia magna) <b>plidynetrimethyl trimethacrylate</b> h acute toxicity study) L (daphnia magna) <b>tert-butyl-p-cresol</b> (daphnia magna) (Fish acute toxicity study) (Algea, gowth inhibition test)	riteria are not met.
STOT-rep Aspiration SECTIO 12.1 Toxic Aquatic to CAS: 67-6 LC50/96h EC50/48h CAS: 3290 LC50/96h EC50/48h LC50/96h EC50/48h LC50/96h EC50/72h 12.2 Persis	eated expo hazard Ba N 12: Ec ity xicity: 4-1 aceton 5540 mg/l 6100 mg/l 0-92-4 prop 2 mg/l (Fi >9.22 mg/ 37-0 2,6-di >0.57 mg/ >0.42 mg/ >0.42 mg/ stence and	or dizziness. <b>ure</b> Based on available data, the classific red on available data, the classification cr <b>plogical information</b> (Fish acute toxicity study) (daphnia magna) <b>plidynetrimethyl trimethacrylate</b> th acute toxicity study) (daphnia magna) <b>tert-butyl-p-cresol</b> (daphnia magna) (Fish acute toxicity study) (Algea, gowth inhibition test) <b>legradability</b> No further relevant informa	riteria are not met.
STOT-rep Aspiration SECTIO 12.1 Toxic Aquatic to CAS: 67-6 LC50/96h EC50/48h CAS: 3290 LC50/96h EC50/48h LC50/96h EC50/72h 12.2 Persis 12.3 Bioac	eated expo hazard Ba N 12: Ec ity xicity: 4-1 aceton 5540 mg/l 6100 mg/l 0-92-4 prop 2 mg/l (Fi >9.22 mg/ 37-0 2,6-di >0.57 mg/ >0.42 mg/ >0.42 mg/ stence and ccumulative	or dizziness. <b>ure</b> Based on available data, the classific red on available data, the classification cr <b>plogical information</b> <b>Plogical informati</b>	riteria are not met.
STOT-rep. Aspiration SECTIO 12.1 Toxic Aquatic to CAS: 67-6 LC50/96h EC50/48h CAS: 3290 LC50/96h EC50/48h LC50/96h EC50/48h LC50/96h EC50/72h 12.2 Persis 12.3 Bioac 12.4 Mobil	eated expo hazard Ba N 12: Ec ity xicity: 4-1 aceton 5540 mg/l 6100 mg/l 6100 mg/l 2 mg/l (Fi >9.22 mg/ 37-0 2,6-di >0.57 mg/ >0.42 mg/ >0.42 mg/ >0.42 mg/ stence and ccumulative lity in soil	or dizziness. <b>ure</b> Based on available data, the classific red on available data, the classification cr <b>plogical information</b> (Fish acute toxicity study) (daphnia magna) <b>plidynetrimethyl trimethacrylate</b> th acute toxicity study) (daphnia magna) <b>tert-butyl-p-cresol</b> (daphnia magna) (Fish acute toxicity study) (Algea, gowth inhibition test) <b>legradability</b> No further relevant informa	riteria are not met.
STOT-rep. Aspiration Aspiration 12.1 Toxic Aquatic to CAS: 67-6 LC50/96h EC50/48h CAS: 3290 LC50/96h EC50/48h LC50/96h EC50/48h LC50/96h EC50/72h 12.2 Persis 12.3 Bioac 12.4 Mobil Ecotoxical	eated expo hazard Ba N 12: Ec ity xicity: 4-1 aceton 5540 mg/l 6100 mg/l 6100 mg/l 0-92-4 prop 2 mg/l (Fi >9.22 mg/ 37-0 2,6-di >0.57 mg/ >0.42 mg/ >0.42 mg/ >0.42 mg/ stence and ccumulative lity in soil l effects:	or dizziness. <b>are</b> Based on available data, the classific red on available data, the classification cr <b>clogical information</b> <b>clogical informati</b>	riteria are not met.
STOT-rep Aspiration SECTIO 12.1 Toxic Aquatic to CAS: 67-6 LC50/96h EC50/48h CAS: 3290 LC50/96h EC50/48h LC50/96h EC50/48h LC50/96h EC50/72h 12.2 Persis 12.3 Bioac 12.4 Mobil Ecotoxical Remark: F	eated expo hazard Ba N 12: Ec ity xicity: 4-1 aceton 5540 mg/l 6100 mg/l 6100 mg/l 9.22 mg/ 2 mg/l (Fi >9.22 mg/ 37-0 2,6-da >0.57 mg/ >0.42 mg/ >0.42 mg/ >0.42 mg/ stence and ccumulative lity in soil l effects: Harmful to	or dizziness. are Based on available data, the classific red on available data, the classification cr ological information Fish acute toxicity study) (daphnia magna) olidynetrimethyl trimethacrylate th acute toxicity study) (daphnia magna) tert-butyl-p-cresol (daphnia magna) (Fish acute toxicity study) (Algea, gowth inhibition test) legradability No further relevant information potential No further relevant information of urther relevant information available. sh	riteria are not met.
STOT-rep Aspiration SECTIO 12.1 Toxic Aquatic to CAS: 67-6 LC50/96h EC50/48h CAS: 3290 LC50/96h EC50/48h LC50/96h EC50/48h LC50/96h EC50/72h 12.2 Persis 12.3 Bioac 12.4 Mobil Ecotoxical Remark: F	eated expo hazard Ba N 12: Ec ity xicity: 4-1 aceton 5540 mg/l 5540 mg/l 6100 mg/l 6100 mg/l 9.22 mg/ 2 mg/l (Fi >9.22 mg/ 37-0 2,6-dt >0.42 mg/ >0.42 mg/ >0.42 mg/ stence and ccumulative lity in soil effects: Harmful to l ecological	or dizziness. <b>are</b> Based on available data, the classific red on available data, the classification cr <b>clogical information</b> <b>clogical informati</b>	riteria are not met.
STOT-rep Aspiration Aspiration SECTIO 12.1 Toxic Aquatic to CAS: 67-6 LC50/96h EC50/48h CAS: 3290 LC50/96h EC50/48h LC50/96h EC50/48h LC50/96h EC50/72h 12.2 Persis 12.3 Bioac 12.4 Mobil Ecotoxical Remark: H Additional General no Do not allo	eated expo hazard Ba N 12: Ec ity xicity: 4-1 aceton 5540 mg/l 5540 mg/l 6100 mg/l 6100 mg/l 9-92-4 prop 2 mg/l (Fi >9.22 mg/ 37-0 2,6-dt >0.42 mg/ >0.42 mg/ >0.42 mg/ >0.42 mg/ stence and ccumulative lity in soil l effects: Harmful to l ecological otes: ow product	or dizziness. are Based on available data, the classific red on available data, the classification cr ological information Fish acute toxicity study) (daphnia magna) olidynetrimethyl trimethacrylate h acute toxicity study) L (daphnia magna) tert-butyl-p-cresol (daphnia magna) (Fish acute toxicity study) (Algea, gowth inhibition test) legradability No further relevant information fo further relevant information available. sh information: to reach ground water, water course or se	riteria are not met.
STOT-rep Aspiration Aspiration SECTIO 12.1 Toxic Aquatic to CAS: 67-6 LC50/96h EC50/48h CAS: 3290 LC50/96h EC50/48h LC50/96h EC50/48h LC50/96h EC50/72h 12.2 Persis 12.3 Bioac 12.4 Mobi Ecotoxical Remark: H Additional General m Do not allo Danger to	eated expo hazard Ba N 12: Ec ity xicity: 4-1 aceton 5540 mg/l 6100 mg/l 6100 mg/l 6100 mg/l 6100 mg/l 9.922 mg/ 2 mg/l (Fi >9.22 mg/ 37-0 2,6-di >0.57 mg/ >0.42 mg/ >0.42 mg/ >0.42 mg/ stence and cumulativ, lity in soil l effects: Harmful to l effects: by product drinking w	or dizziness. are Based on available data, the classific red on available data, the classification cr <b>clogical information</b> <b>Fish acute toxicity study</b> ) (daphnia magna) <b>Context and Secure Study</b> ) (daphnia magna) <b>Context and Secure Study</b> ) (daphnia magna) (Fish acute toxicity study) (Algea, gowth inhibition test) <b>Context and Secure Study</b> (Algea, gowth inhibition test) <b>Context and Secure Secure</b>	riteria are not met.
STOT-rep Aspiration Aspiration SECTIO 12.1 Toxic Aquatic to CAS: 67-6 LC50/96h EC50/48h CAS: 3290 LC50/96h EC50/48h LC50/96h EC50/48h LC50/96h EC50/72h 12.2 Persis 12.3 Bioac 12.4 Mobil Ecotoxical Remark: H Additional General no Do not allo	eated expo hazard Ba N 12: Ec ity xicity: 4-1 aceton 5540 mg/l 6100 mg/l 6100 mg/l 6100 mg/l 6100 mg/l 9.922 mg/ 2 mg/l (Fi >9.22 mg/ 37-0 2,6-di >0.57 mg/ >0.42 mg/ >0.42 mg/ >0.42 mg/ stence and cumulativ, lity in soil l effects: Harmful to l effects: by product drinking w	or dizziness. are Based on available data, the classific red on available data, the classification cr <b>clogical information</b> <b>Fish acute toxicity study</b> ) (daphnia magna) <b>Context and Secure Study</b> ) (daphnia magna) <b>Context and Secure Study</b> ) (daphnia magna) (Fish acute toxicity study) (Algea, gowth inhibition test) <b>Context and Secure Study</b> (Algea, gowth inhibition test) <b>Context and Secure Secure</b>	tion available. n available.

Printing date 14.02.2017

Version number 7

Revision: 14.02.2017

(Contd. of page 6)

Trade name: Prime & Bond NT

- · 12.5 Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

# **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 hazardous substances
HP 3	Flammable
HP 4	Irritant - skin irritation and eye damage
HP 5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity
HP 13	Sensitising
HP 14	Ecotoxic

· Uncleaned packaging:

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

14.1 UN-Number ADR, IMDG, IATA	UN1090	
14.2 UN proper shipping name		
ADR	1090 ACETONE mixture	
· IMDG, IATA	ACETONE, MIXTURE	
· 14.3 Transport hazard class(es)		
ADR		
· Class · Label	3 (F1) Flammable liquids. 3	
· IMDG, IATA		
· Class	3 Flammable liquids.	
· Label	3	
· 14.4 Packing group		
· ADR, IMDG, IATA	II	

Printing date 14.02.2017

Version number 7

Revision: 14.02.2017

Trade name: Prime & Bond NT

	(Contd. of page
14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Warning: Flammable liquids.
Danger code (Kemler):	33
• EMS Number:	F- $E$ , $S$ - $D$
· Stowage Category	E
· 14.7 Transport in bulk according to Anne	ex II of
Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
ADR	
· Limited quantities (LQ)	1L
$\cdot$ 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)	lL
$\cdot$ Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
· UN ''Model Regulation'':	UN 1090 ACETONE MIXTURE, 3, II

**SECTION 15: Regulatory information** 

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

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

· Seveso category P5c FLAMMABLE LIQUIDS

• Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t

 $\cdot$  Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t

• REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

• 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.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

(Contd. on page 9)

Printing date 14.02.2017

Version number 7

Revision: 14.02.2017

#### Trade name: Prime & Bond NT

	(Contd. of page 8
411 Toxic to aquatic life with long lasting effects.	
epartment issuing SDS: Research & Developmen	nt
<b>Intact:</b> HotLine for urgent technical support: +4	
bbreviations and acronyms:	
	ngereuses par Route (European Agreement concerning the Internationa
rriage of Dangerous Goods by Road)	gereuses pur Rome (European Agreement concerning the International
DG: International Maritime Code for Dangerous Goods	
TA: International Air Transport Association	
IS: Globally Harmonised System of Classification and Labell	ing of Chemicals
NECS: European Inventory of Existing Commercial Chemica	
INCS: European List of Notified Chemical Substances	
S: Chemical Abstracts Service (division of the American Che	mical Society)
NEL: Derived No-Effect Level (REACH)	
50: Lethal concentration, 50 percent	
950: Lethal dose, 50 percent	
T: Persistent, Bioaccumulative and Toxic	
vB: very Persistent and very Bioaccumulative	
um. Liq. 2: Flammable liquids – Category 2	
in Irrit. 2: Skin corrosion/irritation – Category 2	
e Irrit. 2: Serious eye damage/eye irritation – Category 2	
in Sens. 1: Skin sensitisation – Category 1	
OT SE 3: Specific target organ toxicity (single exposure) – Co	ategory 3
uatic Acute 1: Hazardous to the aquatic environment - acute	aquatic hazard – Category 1
uatic Chronic 1: Hazardous to the aquatic environment - lon	
uatic Chronic 2: Hazardous to the aquatic environment - lon	
uatic Chronic 3: Hazardous to the aquatic environment - lon	g-term aquatic hazard – Category 3
Data compared to the previous version altered.	

# SAFETY DATA SHEET (SDS)

In accordance with Hazard Communication Standard (HCS), 29CFR 1910.1200(g), 2012 revision

# SECTION I – PRODUCT / COMPANY IDENTIFICATION

Product Name: **Tempit®- E TEMPORARY FILLING MATERIAL** Moisture activated eugenol temporary filling material for lost or loose caps Synonyms: Temporary filling material Part (Item) Number: 310031 Company Name: Centrix, Inc. Address: 770 River Road, City, State, Zip: Shelton CT, 06484 Emergency Telephone Number: 203-929-5582 Information Telephone Number: 800-235-5862

#### SECTION II – HAZARD IDENTIFICATION

2.1: Classification
2.1.1: Classification according to Regulation (EC) No 1272/2008 [CLP]
Hazard Class: Skin sensitization
Hazard Category: 1
Hazard Statement: H317

2.2: GHS Label Elements. Hazard Pictograms Signal Word: WARNING () Comparison of the sector of the s

Hazard Statements H317: Sensitization. 1. May cause an allergic skin reaction

Precautionary Statements P261: Avoid breathing vapor P280: Wear protective gloves and eye protection P302+P352: IF ON SKIN: Wash with plenty of water P333+P313: If irritation or rash occurs, get medical advice/attention P391: Collect spillage

#### SECTION III - COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous Components	%	CAS#	EINECS #
Polyethyl Methacrylate	1-10%	9011-14-7	
Barium Sulfate	10-20%	7727-43-7	
Zinc Oxide	1-10%	1314-13-2	215-222-5
Eugenol	1-10%	97-53-0	202-589-1
Exact % content withheld due t	o trade sec	ret restrictions.	

#### **SECTION IV – FIRST AID MEASURES**

Skin: Wash with soap and water

Ingestion: May cause nausea and vomiting. Seek medical attention if persists. DO NOT INDUCE VOMITING

Inhalation: Irritating to respiratory system. May cause coughing, tightness of the chest. Move exposed person to fresh air. Seek medical attention.

Eyes: Flush with copious amounts of water for 15 minutes with eyes wide open. If irritation persists seek medical attention.

#### SECTION V - FIRE-FIGHTING MEASURES

Burning produces irritating, toxic and obnoxious fumes. Suitable extinguishing. Media: Use extinguisher suitable to cause of fire and its surroundings. Special protection equipment: Wear suitable respiratory equipment when necessary.

#### SECTION VI – ACCIDENTAL RELEASE MEASURES

Avoid raising dust. Ensure adequate ventilation of the working area. Wear suitable protective equipment.

#### SECTION VII – HANDLING AND STORAGE

Handling: No handling problems are likely to be encountered provided normal safe practices of hygiene are applied.

Storage: Store in a cool dry place

Containers: Keep containers tightly closed. Store in correctly labelled containers. Incompatibilities: Unknown

#### SECTION VIII – EXPOSURE CONTROLS / PERSONAL PROTECTION

General measures: Wash hands thoroughly after contact with this product. Limits: No data is available Respiratory Protection: Wear suitable respiratory equipment when necessary Eye protection: Goggles / eyeshields Skin protection: Overalls, rubber gloves Hands protection: Overalls, rubber gloves Other equipment: No further information available

#### SECTION IX – PHYSICAL AND CHEMICAL PROPERTIES

 Appearance: White Stiff Paste
 Explosion limits: N/A

 Odor: Odorless
 Water solubility: Insoluble

 Boiling point: N/A
 Evaporation rate: N/A

 Flash point: N/A
 Other Data: Not available or none

#### SECTION X - STABILITY AND REACTIVITY

Stability: Stable, non-reactive Conditions to avoid: Heat. Moisture Materials to avoid: N/A

#### **SECTION XI – TOXICOLOGICAL INFORMATION**

Barium Sulfate: Oral Rat LD50: 15000mg/kg Eugenol: Oral Rat LD50: 1930mg/kg Polyethyl methacrylateOral Rat LD50: 5000mg/kg

SECTION XII – ECOLOGICAL INFORMATION No data is available

#### SECTION XIII – DISPOSAL CONSIDERATIONS

Dispose in accordance with local authorities

## SECTION XIV - TRANSPORT INFORMATION

Not classified as dangerous goods

#### SECTION XV – REGULATORY INFORMATION No data is available

#### SECTION XVI – OTHER INFORMATION None

**CAUTION:** The above information is based on presently available data and to our best knowledge for handling the product under normal conditions. Any use of this product in any way not indicated on this document or using it together with any other process/procedure will be exclusively under the user's responsibility.

# centrux

#### CENTRIX INCORPORATED

770 River Road, Shelton, CT 06484 USA (203) 929-5582 • (800) 235-5862 • FAX (203) 929-6804 www.centrixdental.com

EC REP Dental-Contact Vertriebs OHG, Im Spiet 101, DE 26506 Norden

Makina Dentistrv Easier.<sup>sa</sup> \_

#### EMERGO AUSTRALIA Level 20, Tower II, Darling Park, 201 Sussex Street Sydney, NSW 2000, Australia