

Revision Date 01/28/2018

Revision 4

## SAFETY DATA SHEET

### BISTITE II Paste A / B

#### 1. IDENTIFICATION

<b>Product Name</b>	BISTITE II Paste A / B
<b>Identified uses</b>	Dental Cement, a component of kit. For dental professionals only.
<b>Supplier</b>	Tokuyama Dental America Inc. Tel: (877) 378 3548 (Toll-Free) <a href="http://www.tokuyama-dental.com/tdc/contact.html">http://www.tokuyama-dental.com/tdc/contact.html</a>
<b>Contact Person</b>	
<b>Manufacturer</b>	Tokuyama Dental Corporation 38-9, Taitou 1-chome, Taitou-ku, Tokyo 110-0016, Japan TEL: +81-3-3835-2261
<b>Emergency Telephone</b>	<p>California Poison Control System - San Francisco Division San Francisco General Hospital Bldg 5 Rm 2A21, 1001 Potrero Ave, San Francisco Emergency telephone number: 1 800 222 1222 E-mail address: <a href="mailto:coadmin@calpoison.org">coadmin@calpoison.org</a> <a href="http://www.calpoison.org">http://www.calpoison.org</a></p> <p>National Capital Poison Center 3201 New Mexico Ave, Ste 310, Washington DC Emergency telephone number: 1 800 222 1222 Telephone number: +1 202 362 3867 Facsimile number: +1 202 362 8377 E-mail address: <a href="mailto:pc@poison.org">pc@poison.org</a> <a href="http://www.poison.org">http://www.poison.org</a></p>

#### 2. HAZARD(S) IDENTIFICATION

<b>Appearance</b>	Paste
<b>Color</b>	White to brown
<b>Odor</b>	No information available.
<b>GHS Pictogram</b>	



**Signal Word** Warning

#### Hazard Statements

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

#### Precautionary Statements

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P261	Avoid breathing vapour/spray.
P302+352	IF ON SKIN: Wash with plenty of soap and water.

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P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P403+233 Store in a well-ventilated place. Keep container tightly closed.  
 P501 Dispose of contents/container in accordance with local regulations.

**Contains**

11-methacryloxy-1,1-undecanedicarboxylic acid (MAC-10)  
 2-DIMETHYLAMINOETHYL METHACRYLATE  
 BENZOYL PEROXIDE  
 bisphenol A polyethoxy dimethacrylate  
 NEOPENTANEDIOL DIMETHACRYLATE

**GHS Classification**

Physical and Chemical Hazards Not classified.  
 Human health Skin Irrit. 2 - H315; Eye Irrit. 2 - H319; Skin Sens. 1 - H317; STOT SE 3 - H335  
 Environment Not classified.

**Hazard Not Otherwise Classified (HNOC)**

Not applicable.

**OSHA Regulatory Status**

This Product is Hazardous under the OSHA Hazard Communication Standard.

**General Information**

IF SWALLOWED: Slightly Irritating. ( DIGESTIVE SYSTEM. ) This chemical may cause skin/eye irritation. May cause sensitization by skin contact.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

**11-methacryloxy-1,1-undecanedicarboxylic acid**

**1-5%**

**CAS No.: 108362-85-2**

**EC No.:**

GHS Classification

Skin Irrit. 2 - H315; Eye Irrit. 2 - H319; STOT SE 3 - H335

**2-DIMETHYLAMINOETHYL METHACRYLATE**

**<1%**

**CAS No.: 2867-47-2**

**EC No.: 220-688-8**

GHS Classification

Acute Tox. 4 - H302; Acute Tox. 4 - H312; Skin Irrit. 2 - H315; Eye Irrit. 2 - H319; Skin Sens. 1 - H317

**BENZOYL PEROXIDE**

**<1%**

**CAS No.: 94-36-0**

**EC No.: 202-327-6**

GHS Classification

Org. Perox. B - H241; Eye Irrit. 2 - H319; Skin Sens. 1 - H317

**bisphenol A polyethoxy dimethacrylate**

**5-10%**

**CAS No.: 41637-38-1**

**EC No.: 609-946-4**

GHS Classification

Skin Irrit. 2 - H315; Eye Irrit. 2 - H319; Skin Sens. 1 - H317; STOT SE 3 - H335

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<b>camphorquinone</b> <span style="float: right;">&lt;1%</span>  <b>CAS No.: 10373-78-1</b> <span style="margin-left: 150px;"><b>EC No.: 233-814-1</b></span>
GHS Classification Skin Irrit. 2 - H315 ; Eye Irrit. 2 - H319 ; STOT SE 3 - H335
<b>dibutyl hydroxy toluene</b> <span style="float: right;">&lt;1%</span>  <b>CAS No.: 128-37-0</b> <span style="margin-left: 150px;"><b>EC No.: 204-881-4</b></span>
GHS Classification Aquatic Chronic 1 - H410
<b>MEQUINOL</b> <span style="float: right;">&lt;1%</span>  <b>CAS No.: 150-76-5</b> <span style="margin-left: 150px;"><b>EC No.: 205-769-8</b></span>
GHS Classification Acute Tox. 4 - H302; Eye Irrit. 2 - H319; Skin Sens. 1 - H317
<b>N,N-DIMETHYL-PARA-TOLUIDINE</b> <span style="float: right;">&lt;1%</span>  <b>CAS No.: 99-97-8</b> <span style="margin-left: 150px;"><b>EC No.: 202-805-4</b></span>
GHS Classification Acute Tox. 3 - H301; Acute Tox. 3 - H311; Acute Tox. 3 - H331; STOT RE 2 - H373; Aquatic Chronic 3 - H412
<b>NEOPENTANEDIOL DIMETHACRYLATE</b> <span style="float: right;">10-30%</span>  <b>CAS No.: 1985-51-9</b> <span style="margin-left: 150px;"><b>EC No.: 217-856-8</b></span>
GHS Classification Skin Irrit. 2 - H315; Eye Irrit. 2 - H319; STOT SE 3 - H335

#### 4. FIRST-AID MEASURES

##### Description of first aid measures

###### **General Information**

Move the exposed person to fresh air at once. Get medical attention if any discomfort continues.

###### **Inhalation**

Move the exposed person to fresh air at once.

###### **Ingestion**

Try to induce vomiting. Get medical attention if any discomfort continues.

###### **Skin Contact**

Wash the skin immediately with soap and water.

###### **Eye Contact**

Make sure to remove any contact lenses from the eyes before rinsing. Promptly wash eyes with plenty of water while lifting the eye lids. Continue to rinse for at least 15 minutes. Contact physician if irritation persists.

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### Most important symptoms and effects, both acute and delayed

#### **Inhalation**

Not irritating.

#### **Ingestion**

Slightly irritating. ( DIGESTIVE SYSTEM. )

#### **Skin Contact**

Slightly irritating. May cause sensitization by skin contact.

#### **Eye Contact**

Slightly irritating.

### Indication of any immediate medical attention and special treatment needed

#### **Notes To The Physician**

Treat Symptomatically. Wear suitable protective clothing.

## 5. FIRE-FIGHTING MEASURES

#### **Auto Ignition Temperature (°C)**

Not available.

#### **Flammability Limit - Lower(%)**

Not available.

#### **Flammability Limit - Upper(%)**

Not available.

#### **Flash point (°C)**

Not available.

#### **Extinguishing Media**

Fire can be extinguished using: Foam. Carbon dioxide or dry powder.

#### **Specific Hazards**

When heated and in case of fire, irritating vapors/gases may be formed.

#### **Special Fire Fighting Procedures**

Avoid breathing fire vapors.

#### **Protective Equipment For Fire-Fighters**

Wear full protective clothing.

## 6. ACCIDENTAL RELEASE MEASURES

#### **Personal Precautions**

Wear protective clothing as described in Section 8 of this material safety data sheet.

#### **Environmental Precautions**

Avoid discharge into drains, water courses or onto the ground.

#### **Spill Clean Up Methods**

Extinguish all ignition sources. Avoid sparks, flames, heat and smoking. Ventilate. Absorb in vermiculite, dry sand or earth and place into containers.

#### **Reference to other sections**

For personal protection, see section 8. For waste disposal, see section 13.

## 7. HANDLING AND STORAGE

#### **Handling**

All handling to take place in well-ventilated area.

#### **Storage**

Store under refrigerated conditions at temperatures between 0 to 10°C (32 to 50°F). Keep away from heat, direct sunlight, sparks and open flames.

#### **Storage Class**

Chemical storage.

#### **Specific end use(s)**

The identified uses for this product are detailed in Section 1.2.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## BISTITE II Paste A / B

COMPONENT	STD	TWA (8-hrs)		STEL (15 min)		Notes
BENZOYL PEROXIDE	PEL		5 mg/m <sup>3</sup>			
BENZOYL PEROXIDE	ACGIH		5 mg/m <sup>3</sup>			A4
dibutyl hydroxy toluene	ACGIH		2 mg/m <sup>3</sup>			A4

  

COMPONENT	IDLH
BENZOYL PEROXIDE	1500 mg/m <sup>3</sup>

ACGIH=American Conference of Governmental Industrial Hygienists.

A4: Not Classifiable as a Human Carcinogen.

### Protective Equipment



### Engineering Measures

Provide adequate general and local exhaust ventilation.

### Respiratory Equipment

In case of inadequate ventilation use suitable respirator.

### Hand Protection

Wear protective gloves.

### Eye Protection

Wear approved safety goggles.

### Other Protection

Wear appropriate clothing to prevent any possibility of skin contact.

### Hygiene Measures

DO NOT SMOKE IN WORK AREA! Wash hands at the end of each work shift and before eating, smoking and using the toilet. Wash promptly with soap & water if skin becomes contaminated. Promptly remove any clothing that becomes contaminated. Use appropriate skin cream to prevent drying of skin. When using do not eat, drink or smoke.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance</b>	Paste
<b>Color</b>	White to brown
<b>Odor</b>	No information available.
<b>Solubility</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Melting point (°C)</b>	Not available.
<b>Relative density</b>	Not available.
<b>Vapor density (air=1)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>pH-Value, Conc. Solution</b>	Not available.
<b>pH-Value, Diluted Solution</b>	Not available.
<b>Viscosity</b>	Not available.

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**Decomposition temperature (°C)**

Not available.

**Odour Threshold, Lower**

Not available.

**Odour Threshold, Upper**

Not available.

**Flash point**

Not available.

**Auto Ignition Temperature (°C)**

Not available.

**Flammability Limit - Lower(%)**

Not available.

**Flammability Limit - Upper(%)**

Not available.

**Partition Coefficient**

(N-Octanol/Water)

Not available.

**Explosive properties**

Not available.

**Other Flammability**

Not available.

**Oxidising properties**

Not available.

Contains Organic peroxides/hydroperoxides.

### 10. STABILITY AND REACTIVITY

**Reactivity**

May polymerise.

**Stability**

Stable under normal temperature conditions and recommended use.

Hazardous reactions:

Not available.

**Conditions To Avoid**

Keep away from heat, sparks and open flame. Protect against direct sunlight.

**Materials To Avoid**

Strong oxidizing agents.

**Hazardous Decomposition Products**

Toxic gases are generated when heated.

### 11. TOXICOLOGICAL INFORMATION

**Acute toxicity:**

Not available.

**Skin Corrosion/Irritation:**

Slightly irritating.

**Serious eye damage/irritation:**

Slightly Irritating.

**Respiratory or skin sensitisation:****Respiratory sensitisation**

Not available.

**Skin sensitisation**

May cause sensitization by skin contact.

**Germ cell mutagenicity:**

Not available.

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### Carcinogenicity:

#### **Carcinogenicity**

Not available.

#### **IARC Carcinogenicity**

Butylated hydroxytoluene (BHT) , BENZOYL PEROXIDE : IARC Group 3 Not classifiable as to its carcinogenicity to humans.

#### **NTP - Carcinogenicity**

Not listed.

#### **OSHA - Carcinogenicity**

Not listed.

### Reproductive Toxicity:

Not available.

### Specific target organ toxicity - single exposure:

#### **STOT - Single exposure**

Not available.

### Specific target organ toxicity - repeated exposure:

#### **STOT - Repeated exposure**

Not available.

### Aspiration hazard:

#### **Viscosity**

Not available.

## 12. ECOLOGICAL INFORMATION

### **Toxicity**

No data available.

### **Degradability**

No data available.

### **Bioaccumulative potential**

No data available on bioaccumulation.

### **Partition coefficient**

Not available.

### **Mobility:**

No information available.

### **Results of PBT and vPvB assessment**

This product does not contain any PBT or vPvB Substances.

### **Other adverse effects**

Not known.

## 13. DISPOSAL CONSIDERATIONS

### **Disposal Methods**

Dispose of waste and residues in accordance with local authority requirements.

## 14. TRANSPORT INFORMATION

**General** Not regulated.

**UN No. (DOT/TDG)** N/A

**UN No. (IMDG)** N/A

**UN No. (ICAO)** N/A

**DOT Proper Shipping Name** Not applicable.

### **DOT Hazard Class**

No classification noted.

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### DOT Hazard Label

No DOT label requirement noted

**IMDG Class** Not applicable.

**ICAO Class** Not applicable.

### Transport Labels

No transport warning sign required.

**DOT Pack Group** Not applicable.

**IMDG Pack Group** Not applicable.

**Air Pack Group** Not applicable.

### Environmentally Hazardous Substance/Marine Pollutant

No.

**Special precautions for user** Not available.

### Transport in Bulk according to Annex II of MARPOL 73/78 and the IBC Code Notes

Not applicable.

## 15. REGULATORY INFORMATION

### Regulatory Status (US)

This Product is Hazardous under the OSHA Hazard Communication Standard. California Proposition 65. Warning : N,N-DIMETHYL-PARA-TOLUIDINE  
This product contains a chemical known to the State of California to cause cancer.

**Regulatory References** 29 CFR 1910. 1200(g) Federal Regulations (OSHA Standard).

### US Federal Regulations

#### **SARA Section 302 Extremely Hazardous Substances Tier II Threshold Planning Quantities**

None of the ingredients are listed.

#### **CERCLA/Superfund, Hazardous Substances/Reportable Quantities (EPA)**

None of the ingredients are listed.

#### **SARA Extremely Hazardous Substances EPCRA Reportable Quantities**

None of the ingredients are listed.

#### **SARA 313 Emission Reporting**

The following ingredients are listed.

BENZOYL PEROXIDE 1.0%

#### **CAA Accidental Release Prevention**

None of the ingredients are listed.

#### **SARA (311/312) Hazard Categories**

Acute

#### **OSHA Highly Hazardous Chemicals**

None of the ingredients are listed.

### US State Regulations

#### **California Proposition 65 Carcinogens and Reproductive Toxins**

The following ingredients are listed.

N, N-DIMETHYL-PARA-TOLUIDINE; Known to the State of California to cause cancer.

#### **California Air Toxics "Hot Spots" (A-I)**

The following ingredients are listed.

BENZOYL PEROXIDE

#### **California Air Toxics "Hot Spots" (A-II)**

None of the ingredients are listed.

#### **Massachusetts "Right To Know" List**

The following ingredients are listed.

2-DIMETHYLAMINOETHYL METHACRYLATE

BENZOYL PEROXIDE

dibutyl hydroxy toluene

MEQUINOL



## BISTITE II Paste A / B

### Rhode Island "Right To Know" List

The following ingredients are listed.

BENZOYL PEROXIDE  
dibutyl hydroxy toluene  
MEQUINOL

### Minnesota "Right To Know" List

The following ingredients are listed.

BENZOYL PEROXIDE  
dibutyl hydroxy toluene  
MEQUINOL

### New Jersey "Right To Know" List

The following ingredients are listed.

2-DIMETHYLAMINOETHYL METHACRYLATE  
BENZOYL PEROXIDE  
dibutyl hydroxy toluene  
MEQUINOL

### Pennsylvania "Right To Know" List

The following ingredients are listed.

2-DIMETHYLAMINOETHYL METHACRYLATE  
BENZOYL PEROXIDE  
dibutyl hydroxy toluene  
MEQUINOL

### International Inventories

#### EU - EINECS/ELINCS

The following ingredients are listed.

2-DIMETHYLAMINOETHYL METHACRYLATE  
BENZOYL PEROXIDE  
camphorquinone  
dibutyl hydroxy toluene  
MEQUINOL  
N, N-DIMETHYL-PARA-TOLUIDINE  
NEOPENTANEDIOL DIMETHACRYLATE

#### Canada – DSL/NDL

The following ingredients are listed.

2-DIMETHYLAMINOETHYL METHACRYLATE  
BENZOYL PEROXIDE  
bisphenol A polyethoxy dimethacrylate  
camphorquinone  
dibutyl hydroxy toluene  
MEQUINOL  
N, N-DIMETHYL-PARA-TOLUIDINE

#### US - TSCA

The following ingredients are listed.

2-DIMETHYLAMINOETHYL METHACRYLATE  
BENZOYL PEROXIDE  
bisphenol A polyethoxy dimethacrylate  
camphorquinone  
dibutyl hydroxy toluene  
MEQUINOL  
N, N-DIMETHYL-PARA-TOLUIDINE  
NEOPENTANEDIOL DIMETHACRYLATE

#### US – TSCA 12(b) Export Notification

None of the ingredients are listed.

### 16. OTHER INFORMATION

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## BISTITE II Paste A / B

### Disclaimer

The information which is contained in this document is based on available data. However, as such has been obtained from various sources, including independent laboratories, it is given without warranty or representation that is complete, accurate and can be relied upon. Tokuyama Dental Corp. has not attempted to conceal in any way the deleterious aspects of the product listed herein, but makes no warranty as to such information.