Safety Data Sheet
Trade Name: **Cosmedent Complete Universal Adhesive System**

### 1.0 Commercial Product Name and Supplier

1.1 Commercial product name / designation
- Cosmedent Complete Light-Cure Primer & Unfilled Resin
- Cosmedent Complete Dual-Cure Catalyst
- Cosmedent Complete Light-Cure Unfilled Resin

1.2 Application / Use
Dental bonding agent for use by dentists.

1.2.2 SIC
851 Human health activity

1.2.3 Use Category
55

1.3 Company Name
**Cosmedent, Inc.**
401 N. Michigan Ave., Suite 2500
Chicago, IL 60611

1.4 Emergency Telephone Number
1-800-535-5053 (24 hours USA)

1.5 Telephone Number for Information
312-644-9586 or 800-621-6729

### 2.0 Hazards Identification

2.1 Classification

2.1.1 Classification according to Regulation (EC) No. 1272/2008 [CLP]
<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Hazard Category</th>
<th>Hazard Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammable liquid</td>
<td>2</td>
<td>H225</td>
</tr>
<tr>
<td>Eye irritation</td>
<td>2</td>
<td>H319</td>
</tr>
<tr>
<td>STOT SE</td>
<td>3</td>
<td>H335</td>
</tr>
<tr>
<td>Skin irritation</td>
<td>2</td>
<td>H315; EUH066</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>1</td>
<td>H317</td>
</tr>
</tbody>
</table>

2.1.2 Classification according to Directive 67/548/EEC
(See SECTION 16 for full text of risk phrases)
- Flammable (F), Irritant (Xi). R11-36/37/38; R43; R66

### 2.2 GHS Label Elements

- Hazard Pictograms

- Signal Word: **DANGER**

- **Restricted to use by dental professional only**

- **Hazard Statements:**
  - H319: Causes serious eye irritation. Category 2.
  - H335: Specific Target Organ Toxicity (STOT), single exposure, respiratory tract, Category 3: May cause respiratory irritation.
  - H315: Causes skin irritation. Category 2.
  - H317: May cause an allergic skin reaction. Category 2.
  - EUH066: Repeated exposure may cause skin dryness or cracking.

- **Precautionary Statements:**
  - P210: Keep away from heat, sparks, open flame, hot surfaces. No smoking.
  - P403+P233: Store in a well-ventilated place. Keep container tightly closed.
Safety Data Sheet

Trade Name: **Cosmedent Complete Universal Adhesive System**

- P261: Avoid breathing fumes.
- P280: Wear protective gloves/ clothing and eye protection.
- P304+P340: If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing.
- P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P303+P361+P353: If on skin or hair, remove contaminated clothing. Rinse skin with water.
- P370+P378: In case of fire, use dry chemical, alcohol foam, or carbon dioxide for extinction.

### 3.0 Composition

#### 3.1 Chemical characterization of the preparation:
Methacrylate ester monomers in acetone vehicle.

#### 3.2 Hazardous ingredients

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Name of the ingredient</th>
<th>Concentration</th>
<th>Classification according to 67/548/EEC</th>
<th>Classification according to Regulation (EC) No.1272/2008 (CLP).</th>
</tr>
</thead>
<tbody>
<tr>
<td>67-64-1</td>
<td>Acetone (Complete Light-Cure Unfilled Resin only)</td>
<td>50% to 80%</td>
<td>Flammable (F); Irritant (X); R11- 36/37/38-66</td>
<td>Flammable liquid; Category 2; Eye irritation; Category 2; STOT SE; Category 3; Skin irritation; Category 2</td>
</tr>
<tr>
<td>----</td>
<td>Methacrylate ester monomers</td>
<td>5% to 50%</td>
<td>Irritant (X); R 43</td>
<td>Skin sensitization; Category 1</td>
</tr>
</tbody>
</table>

### 4.0 First Aid Measures

#### 4.1 General Information
Acetone may cause irritation of eyes or skin on contact. Exposure to >750 ppm may cause irritation of respiratory tract, mucous membranes. Methacrylate may cause sensitization of skin with prolonged/repeated contact. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.

#### 4.2 Eye Contact
Keep eyelids apart; flush with running water for 15+ minutes. Get medical attention.

#### 4.3 Skin Contact
Remove contaminated clothing. Immediately wash skin well with mild soap and running water. Use hand cream. Get medical attention if irritation persists.

#### 4.4 Ingestion
Rinse mouth with water. Drink water to dilute, but only if person is conscious. Do not induce vomiting. Get immediate medical attention.

#### 4.5 Inhalation
Move to fresh air. If necessary, administer oxygen and/or artificial respiration and seek medical attention.

#### 4.6 Precautions for first responders
Ventilate the area. Wear safety glasses and gloves to prevent contact.

#### 4.7 Information for physicians

**Symptoms**
Irritation, pain or redness in eyes, throat or on skin. Headache, fatigue. Nervous system depressant.

**Hazards**
Acetone may cause irritation of eyes or skin on contact. Exposure to >750 ppm may cause irritation of respiratory tract and mucous membranes. Persons with chronic respiratory or skin disease are at increased risk with prolonged exposure to acetone. Methacrylate may cause sensitization of skin with prolonged and/or repeated contact.
Safety Data Sheet

Trade Name: **Cosmedent Complete Universal Adhesive System**

### 5.0 Fire Fighting Measures

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Same as above under First Aid.</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1</td>
<td>Suitable extinguishing media</td>
</tr>
<tr>
<td>5.2</td>
<td>Extinguishing media to avoid</td>
</tr>
<tr>
<td>5.3</td>
<td>Special exposure hazards in a fire</td>
</tr>
<tr>
<td>5.4</td>
<td>Special protective equipment for firefighters</td>
</tr>
</tbody>
</table>

#### 5.1 Suitable extinguishing media

Use dry chemical, alcohol foam, or carbon dioxide.

#### 5.2 Extinguishing media to avoid

Water may be ineffective, but will keep fire-exposed containers cool.

#### 5.3 Special exposure hazards in a fire

Thermal decomposition may produce toxic oxides of carbon.

#### 5.4 Special protective equipment for firefighters

Self-contained breathing apparatus

### 6.0 Accidental Release Measures

| Personal precautions. | Wear chemical splash goggles, gloves and lab coat. |
| Environmental precautions | Avoid releasing large quantities into environment. |
| Method for clean up | Wear gloves and safety glasses. Wipe up with paper towels or cloths. Rinse area of spill with soap and water. Place all absorbent material in closed container away from heat, sparks, sun and oxidizers. |

### 7.0 Handling and Storage

| Handling | Avoid cross-contamination. Avoid heat, ignition sources, and intense light. Empty containers may retain residual product; handle appropriately. |
| Storage | Replace cap over applicator tip immediately after use. Keep tightly capped in original container. Store at cool room temperature in a well-ventilated area. Avoid extremes of temperature (>27°C/80°F, <5°C/40°F), sparks, direct sunlight, oxidizing agents. Vapor may form flammable mixtures with air. |
| Specific uses | Dental adhesives |

### 8.0 Exposure Controls / Personal Protection

| Exposure limit values | Acetone: 750 ppm |
| Exposure controls | |
| Occupational exposure controls | Wear chemical splash goggles, gloves, lab coat. No other special equipment or ventilation required under normal conditions of use. For large quantities/prolonged exposure, use enclosure, local ventilation and dilution to reduce concentration below TLV. |
| Respiratory protection | Good general ventilation is sufficient to control any airborne vapors. |
| Hand protection | No special requirements other than the usual surgical gloves. |
| Eye protection | Safety glasses. |
| Skin protection | No special requirements. |
| Other controls | Emergency eye wash fountain should be close by. Do not eat, drink or smoke. Avoid contact with eyes, skin or clothing. Avoid breathing vapors. Wash hands after use. |
| Environmental exposure controls | Follow all government regulations. |

### 9.0 Physical and Chemical Properties

| Characteristics | |
**Safety Data Sheet**

**Trade Name:** *Cosmedent Complete Universal Adhesive System*

9.1.1 Appearance / Color / Physical state
- Complete Light-cure Primer & Unfilled Resin: Yellow resinous liquid
- Complete Dual-cure Catalyst: Pale yellow to amber thin liquid
- Complete Light-cure Unfilled Resin: Yellow, oily liquid

9.1.2 Odor
- Complete Light-cure Primer & Unfilled Resin: Mild, characteristic resin odor
- Complete Light-cure Catalyst: Characteristic, sweet, mint-like acetone odor
- Complete Light-cure Unfilled Resin: Mild, characteristic resin odor

9.2 Important health, safety and environmental information

9.2.1 pH
- Not applicable

9.2.2 Boiling point
- Boiling Point: 56.5°C

9.2.3 Flash point
- -18°C (Tag closed cup)

9.2.4 Ignition temperature
- Not determined

9.2.5 Explosive properties
- Lower 2.5 Upper 12.8

9.2.6 Odor threshold
- 159 ppm

9.2.7 Vapor pressure
- 180 mm Hg / 239.98 mbar / Id: E

9.2.8 Specific gravity
- Complete Light-cure Primer & Unfilled Resin: 0.788
- Complete Dual-cure Catalyst: 0.795
- Complete Light-Cure Unfilled Resin: 1.100

9.2.9 Solubility in water
- Acetone: Very soluble. Resins: Insoluble

9.2.10 Partition coefficient
- Not determined

9.2.11 Viscosity
- Not determined

9.2.12 Vapor density
- 2

9.2.13 Evaporation rate
- 6

10.0 Stability and reactivity

10.1 Conditions to avoid
- Heat, sparks, open flame, cross-contamination.

10.2 Materials to avoid
- Acetyl chloride, acids, bases, amines, bromines, chloroform, hydrogen peroxide, strong oxidizers, plastics, rayon, ketones, and acetaldehyde.

10.3 Hazardous decomposition products
- Thermal decomposition may produce toxic oxides of carbon.

10.4 Further information
- Stable if stored and used as directed.

11.0 Toxicological information

11.1 Acute toxicity
- Minimal health hazard under normal conditions of dental practice. Large quantities/prolonged exposure: acetone is a significant health hazard. LD50 in rats: 10.7ml/kg orally. Respiratory irritant at >750 ppm.

11.2 Irritation and corrosiveness
- May cause irritation of eyes or skin on contact. May cause irritation of respiratory tract if inhaled.

11.3 Sensitization
- Prolonged or repeated exposure to methacrylates may cause sensitization.
Safety Data Sheet

Trade Name: **Cosmedent Complete Universal Adhesive System**

11.4 Sub-acute, sub-chronic and prolonged toxicity
No chronic health hazard under normal conditions of use. Prolonged or repeated exposure to methacrylates may cause sensitization. Prolonged/repeated exposure to acetone may cause skin to dry and crack.

11.5 Carcinogenicity, Mutagenicity, Reproductive Toxicity
None known

11.6 Empirical data
None available

11.7 Clinical experience
Dental adhesives have been used for decades with a high benefit-to-risk ratio. There is no evidence of short-term or long-term risk or any problems after thousands of procedures.

12.0 Ecological Information

12.1 Ecotoxicity
Follow good working practices and all government regulations. Avoid release into environment.

13.0 Disposal Considerations

13.1 Regulations
Follow all local and national government regulations in disposing material or contaminated packaging.

14.0 Transport Information

14.1 UN Number
1090

14.2 Technical name
Acetone

14.3 Packing group
Packing Group II

14.4 IATA class
3

15.0 Regulatory Information

15.1 EU
Class IIa Medical Devices under MDD 93/42/EEC.

15.2 US FDA
Class II Medical Devices.

15.3 Health Canada
Class III Medical Devices

16.0 Other information

16.1 List of relevant R phrases
R11: Highly flammable
R 36 / 37 / 38: Irritating to eyes, respiratory system and skin.
R43: May cause sensitization by skin contact
R66: Repeated exposure may cause skin dryness or cracking.

16.2 Hazard Statements
H319: Causes serious eye irritation. Category 2.
H335: Specific Target Organ Toxicity (STOT), single exposure, respiratory tract, Category 3: May cause respiratory irritation.
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#### 16.3 Precautionary Statements

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- **P370+P378:** In case of fire, use dry chemical, alcohol foam, or carbon dioxide for extinction.

#### 16.4 Restrictions on use

Dental adhesives are to be sold to and used by dental professionals only.

#### 16.5 Further information

The information presented herein is believed to be factual as it has been derived from the works of persons believed to be qualified experts. However, nothing contained in this information is to be taken as a warranty or representation for which Cosmedent bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate.

#### 16.5 Sources of key data

- National Institute for Occupational Safety (NIOSH)
- US Occupational Safety and Health Administration (OSHA)

#### 16.6 Information which has been added, deleted or revised.

This Safety Data Sheet has been revised to meet the requirements of the GHS SDS format and Regulations (EC) No. 1272/2008 (CLP) and (EC) No. 1907/2006 (REACH). Specifically, Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified.