

Trade Name: **PULPDENT Orthodontic Bracket Adhesive (OBA)**

| 1.0 Commercial Product Name and Supplier |                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|------------------------------------------|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|------------------------|-------------------------|----------------|---|------|---------|---|------|-----------------|---|------|--------------------|---|------|--|
| 1.1                                      | Commercial product name / designation                                                           | Ortho-Choice™ Orthodontic Bracket Adhesive (OBA)                                                                                                                                                                                                                                                                                                                            |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
| 1.2                                      | Application / Use                                                                               | Dental material for use by dental professional only.                                                                                                                                                                                                                                                                                                                        |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
| 1.2.2                                    | SIC                                                                                             | 851 Human health activity                                                                                                                                                                                                                                                                                                                                                   |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
| 1.2.3                                    | Use Category                                                                                    | 55                                                                                                                                                                                                                                                                                                                                                                          |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
| 1.3                                      | Manufacturer                                                                                    |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | <b>Pulpdent Corporation</b>                                                                     |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | 80 Oakland Street                                                                               | Telephone: 1 617 926-6666                                                                                                                                                                                                                                                                                                                                                   |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | P.O. Box 780                                                                                    | Fax: 1 617 926-6262                                                                                                                                                                                                                                                                                                                                                         |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | Watertown, MA 02472 USA                                                                         | Email: <a href="mailto:Pulpdent@pulpdent.com">Pulpdent@pulpdent.com</a>                                                                                                                                                                                                                                                                                                     |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
| 1.4                                      | Emergency Number                                                                                | 24 Hour Emergency: 1-800-535-5053 (USA)                                                                                                                                                                                                                                                                                                                                     |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
| 1.5                                      | Authorized European Representative                                                              |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | International Business Solutions Ltd.                                                           | Tel: 07989 407479                                                                                                                                                                                                                                                                                                                                                           |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | 54 Mayfield Ridge                                                                               | Fax: 01256 350330                                                                                                                                                                                                                                                                                                                                                           |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | Hatch Warren, Basingstoke, RG22 4RS UK                                                          | Email: <a href="mailto:s.williams5@btconnect.co.uk">s.williams5@btconnect.co.uk</a>                                                                                                                                                                                                                                                                                         |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
| 2.0 Hazards Identification               |                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
| 2.1                                      | Classification                                                                                  | Irritant.                                                                                                                                                                                                                                                                                                                                                                   |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
| 2.1.1                                    | Classification according to Regulation (EC) No 1272/2008 [CLP]                                  | <table><thead><tr><th><u>Hazard Class</u></th><th><u>Hazard Category</u></th><th><u>Hazard Statement</u></th></tr></thead><tbody><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</td></tr><tr><td>Skin sensitization</td><td>1</td><td>H317</td></tr></tbody></table> | <u>Hazard Class</u> | <u>Hazard Category</u> | <u>Hazard Statement</u> | Eye irritation | 2 | H319 | STOT SE | 3 | H335 | Skin irritation | 2 | H315 | Skin sensitization | 1 | H317 |  |
| <u>Hazard Class</u>                      | <u>Hazard Category</u>                                                                          | <u>Hazard Statement</u>                                                                                                                                                                                                                                                                                                                                                     |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
| Eye irritation                           | 2                                                                                               | H319                                                                                                                                                                                                                                                                                                                                                                        |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
| STOT SE                                  | 3                                                                                               | H335                                                                                                                                                                                                                                                                                                                                                                        |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
| Skin irritation                          | 2                                                                                               | H315                                                                                                                                                                                                                                                                                                                                                                        |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
| Skin sensitization                       | 1                                                                                               | H317                                                                                                                                                                                                                                                                                                                                                                        |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
| 2.1.2                                    | Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases) | Xi ( Irritant); R 36/37/38 - 43                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
| 2.2                                      | GHS Label Elements                                                                              |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | Hazard Pictograms                                                                               |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          |              |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | Signal Word: <b>WARNING</b>                                                                     |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | <b>Restricted to use by dental professional only.</b>                                           |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | <b>Hazard Statements</b>                                                                        |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | H319: Eye irritation. 2. May cause eye irritation.                                              |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | H335: STOT SE. 3. May cause respiratory irritation.                                             |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | H315: Skin irritation. 2. May cause skin irritation.                                            |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | H317: Sensitization. 1. May cause an allergic skin reaction.                                    |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | <b>Precautionary Statements</b>                                                                 |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | P261: Avoid breathing vapor.                                                                    |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | P280: Wear protective gloves and eye protection                                                 |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | P305+P351: If in eyes, rinse cautiously with water for several minutes.                         |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | P337+P313: If eye irritation persists, get medical advice/attention.                            |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | P302+P352: If on skin, wash with plenty of soap and water.                                      |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |
|                                          | P333+P313: If irritation or rash occurs, get medical advice/attention.                          |                                                                                                                                                                                                                                                                                                                                                                             |                     |                        |                         |                |   |      |         |   |      |                 |   |      |                    |   |      |  |

Trade Name: **PULPDENT Orthodontic Bracket Adhesive (OBA)**

P410+P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F.

|     |                                              |                                                |                                                                                                                                                                                                                         |                               |                                                                                                       |
|-----|----------------------------------------------|------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-------------------------------------------------------------------------------------------------------|
| 3.0 | Composition                                  |                                                |                                                                                                                                                                                                                         |                               |                                                                                                       |
| 3.1 | Chemical characterization of the preparation |                                                | Glass filler in light-cured aromatic / aliphatic methacrylate resins.                                                                                                                                                   |                               |                                                                                                       |
| 3.2 | Hazardous ingredients                        |                                                |                                                                                                                                                                                                                         |                               |                                                                                                       |
|     | CAS Number                                   | Name of the Ingredient                         | Concentration                                                                                                                                                                                                           | Classification per 67/548/EEC | Classification per Regulation (EC) No.1278/2008 (CLP)                                                 |
|     | Proprietary                                  | Mixture of uncured methacrylate ester monomers | 55-65%                                                                                                                                                                                                                  | Xi (Irritant), R36/37/38; R43 | Eye irritation, 2, H319<br>STOT SE 3, H335<br>Skin irritation, 2, H315<br>Skin sensitization, 1, H317 |
|     | 112945-52-5                                  | Amorphous silica                               | 5.0 %                                                                                                                                                                                                                   | Xi (Irritant), R36/37/38      | Eye irritation, 2, H319<br>STOT SE 3, H335<br>Skin irritation, 2, H315                                |
| 4.0 | First Aid Measures                           |                                                |                                                                                                                                                                                                                         |                               |                                                                                                       |
| 4.1 | General Information                          |                                                | May be irritating to eyes, respiratory system and skin. Do not inhale vapors. May cause sensitization by skin contact. Show this safety data sheet to medical personnel. Seek medical attention in case of uncertainty. |                               |                                                                                                       |
| 4.2 | Inhalation                                   |                                                | Move to fresh air. If necessary, administer oxygen, artificial respiration and seek medical attention.                                                                                                                  |                               |                                                                                                       |
| 4.3 | Skin Contact                                 |                                                | Take off contaminated clothing. Wash skin thoroughly with soap and running water for 15 minutes.                                                                                                                        |                               |                                                                                                       |
| 4.4 | Eye Contact                                  |                                                | Keep eyelids apart, flush with running water for 15+ minutes. Seek medical attention.                                                                                                                                   |                               |                                                                                                       |
| 4.5 | Ingestion                                    |                                                | Rinse mouth with water. Do not induce vomiting. Seek immediate medical attention. May be irritating to mucous membranes.                                                                                                |                               |                                                                                                       |
| 4.6 | Precautions for first responders             |                                                | Ventilate the area. Wear eye and skin protection.                                                                                                                                                                       |                               |                                                                                                       |
| 4.7 | Information for physicians                   |                                                |                                                                                                                                                                                                                         |                               |                                                                                                       |
|     | Symptoms                                     |                                                | Irritation or redness in eyes, throat or on skin.                                                                                                                                                                       |                               |                                                                                                       |
|     | Hazards                                      |                                                | May be irritating to eyes, respiratory system and skin. May cause sensitization by skin contact.                                                                                                                        |                               |                                                                                                       |
|     | Treatment                                    |                                                | As above under First Aid.                                                                                                                                                                                               |                               |                                                                                                       |
| 5.0 | Fire Fighting Measures                       |                                                |                                                                                                                                                                                                                         |                               |                                                                                                       |
| 5.1 | Suitable extinguishing media                 |                                                | Carbon dioxide, dry chemical, alcohol foam, or water fog. Water spray may be used to keep fire exposed containers cool.                                                                                                 |                               |                                                                                                       |
| 5.2 | Extinguishing media to avoid                 |                                                | Do not use direct water stream                                                                                                                                                                                          |                               |                                                                                                       |
| 5.3 | Special exposure hazards in a fire           |                                                | Heat of fire may cause polymerization with rapid release of energy, especially in amounts greater than in this product.                                                                                                 |                               |                                                                                                       |

Trade Name: **PULPDENT Orthodontic Bracket Adhesive (OBA)**

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| 5.4 | Special protective equipment for fire-fighters | Self-contained breathing apparatus. Cool exposed containers with water spray to prevent polymerization under fire conditions. |
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## 6.0 Accidental Release Measures

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| 6.1 | Personal precautions.     | Ventilate area. Wear safety glasses, gloves, and lab coat.                                                                                                     |
| 6.2 | Environmental precautions | Contain uncured, spilled material. Cured/set-up material is, to our knowledge, inert. Follow all government regulations.                                       |
| 6.3 | Method for clean up       | Wipe up spill with suitable material (paper towels or cloths). Collect for disposal in a covered container. Wash area of spill with alcohol or soap and water. |

## 7.0 Handling and Storage

|     |               |                                                                                                                                                                                                                                                                                                                                                                            |
|-----|---------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 7.1 | Handling      | For use only by dental professionals trained in its use. Follow good hygiene practices. Do not smoke, eat or drink while using. Remove applicator tip from syringe and cap container immediately after use. Keep light cure materials shaded from intense light sources.                                                                                                   |
| 7.2 | Storage       | Keep containers tightly closed. Store product in original container at cool room temperature (<25°C) and in a dry, well-ventilated area. Avoid direct, intense light, sources of ignition and extremes of temperature (>80°F/27°C, <40°F/5°C). Shelf life for unopened product is two years from date of manufacture, provided that the material has been stored properly. |
| 7.3 | Specific uses | Dental material                                                                                                                                                                                                                                                                                                                                                            |

## 8.0 Exposure Controls / Personal Protection

|         |                                 |                                                                                                                                            |
|---------|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| 8.1     | Exposure limit values           | PEL: Not established. TLV: Not established.                                                                                                |
| 8.2     | Exposure controls               |                                                                                                                                            |
| 8.2.1   | Occupational exposure controls  | No special equipment required under normal conditions of use of this product in the quantity provided.                                     |
| 8.2.1.1 | Respiratory protection          | None required under normal conditions of use. Good general ventilation is sufficient to control any airborne vapors from uncured material. |
| 8.2.1.2 | Hand protection                 | Protective gloves are recommended.                                                                                                         |
| 8.2.1.3 | Eye protection                  | Safety glasses are recommended                                                                                                             |
| 8.2.1.4 | Skin protection                 | No special requirements, other than good personal hygiene, safety practices and wearing a lab coat.                                        |
| 8.2.1.5 | Other controls                  | Emergency eye wash fountain should be available. Wash hands after use.                                                                     |
| 8.2.2   | Environmental exposure controls | Cure material before disposing.                                                                                                            |

## 9.0 Physical and Chemical Properties

|       |                        |                       |
|-------|------------------------|-----------------------|
| 9.1   | Appearance / Color     |                       |
| 9.1.1 | Color / Physical state | Stiff off-white paste |
| 9.1.2 | Odor                   | Faint, characteristic |

Trade Name: **PULPDENT Orthodontic Bracket Adhesive (OBA)**

9.2 Important health, safety and environmental information

|        |                           |                            |
|--------|---------------------------|----------------------------|
| 9.2.1  | pH                        | Not determined             |
| 9.2.2  | Boiling point             | Not determined             |
| 9.2.3  | Flash point               | Not determined             |
| 9.2.4  | Flammability (solid, gas) | Not applicable             |
| 9.2.5  | Explosive properties      | Not applicable             |
| 9.2.6  | Oxidizing properties      | Not determined             |
| 9.2.7  | Vapor pressure            | < 1 mm Hg / 133 Pa / Id: B |
| 9.2.8  | Specific gravity          | 1.820                      |
| 9.2.9  | Solubility in water       | Nil                        |
| 9.2.10 | Partition coefficient     | Not determined             |
| 9.2.11 | Viscosity                 | Not determined             |
| 9.2.12 | Vapor density             | 1                          |
| 9.2.13 | Evaporation rate          | < 0.1                      |

**10.0 Stability and reactivity**

|      |                                  |                                                                                                                                                                                                                      |
|------|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10.1 | Conditions to avoid              | Temperature > 80°F/27°C, strong visible light.                                                                                                                                                                       |
| 10.2 | Materials to avoid               | Reducing and oxidizing agents, peroxides, amines.                                                                                                                                                                    |
| 10.3 | Hazardous decomposition products | Under fire conditions and with amounts far greater than that supplied in this product, hazardous polymerization may occur with heat build up and release of carbon monoxide, carbon dioxide, and oxides of nitrogen. |
| 10.4 | Further information              | Stable if stored and used as directed. Polymerization will occur when light-cured material is exposed to direct light.                                                                                               |

**11.0 Toxicological information**

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|------|------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 11.1 | Acute toxicity                                       | Not toxic. Minimal health hazard in the quantities present in this product and under normal conditions of use.                                                                                                                  |
| 11.2 | Irritation and corrosiveness                         | May be irritating to eyes, mucous membranes or skin on contact or with prolonged exposure.                                                                                                                                      |
| 11.3 | Sensitization                                        | May be sensitizing. Prolonged or frequent skin contact may cause allergic skin reactions in some susceptible individuals.                                                                                                       |
| 11.4 | Sub-acute, sub-chronic and prolonged toxicity        | Prolonged and/or frequent skin contact may cause allergic skin reactions in susceptible individuals. Prolonged exposure to large amounts (more than in this product) of this material may cause eye and respiratory irritation. |
| 11.5 | Carcinogenicity, Mutagenicity, Reproductive Toxicity | None known                                                                                                                                                                                                                      |
| 11.6 | Empirical data                                       | Not available                                                                                                                                                                                                                   |

Trade Name: **PULPDENT Orthodontic Bracket Adhesive (OBA)**

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| 11.7 | Clinical experience | OBA has been used by dental professionals for over 20 years. During that time there have been no significant complaints regarding safety or effectiveness, no recalls and no adverse events. |
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| <b>12.0</b> | <b>Ecological Information</b> |
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| 12.1 | Eco-toxicity | Avoid release of uncured material into the environment. To the best of our knowledge, polymerized material is inert. No other information is available. Follow all government regulations. |
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| <b>13.0</b> | <b>Disposal Considerations</b> |
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| 13.1 | Regulations | Follow all local and national government regulations in disposing material or contaminated packaging. |
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| <b>14.0</b> | <b>Transport Information</b> |
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| 14.1 | Restrictions | None. Not regulated. |
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| <b>15.0</b> | <b>Regulatory Information</b> |
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|      |                |                                               |
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| 15.1 | EU Regulations | Class IIa medical device under MDD 93/42/EEC. |
|------|----------------|-----------------------------------------------|

|      |        |                         |
|------|--------|-------------------------|
| 15.2 | US FDA | Class II medical device |
|------|--------|-------------------------|

|      |               |                         |
|------|---------------|-------------------------|
| 15.3 | Health Canada | Class II medical device |
|------|---------------|-------------------------|

|             |                          |
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| <b>16.0</b> | <b>Other information</b> |
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|      |                            |                                                                                                  |
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| 16.1 | List of relevant R phrases | R36/37/38, Irritating to eyes, respiratory system and skin.<br>R43, Sensitizing by skin contact. |
|------|----------------------------|--------------------------------------------------------------------------------------------------|

|      |                   |                                                                                                                                                                                                                                                   |
|------|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 16.2 | Hazard Statements | H319: Eye irritation. Hazard category 2.<br>H335: Specific Target Organ Toxicity - Single exposure. Hazard category 3. Respiratory tract irritation.<br>H315: Skin irritation. Hazard category 2.<br>H317: Skin Sensitization. Hazard category 1. |
|------|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|      |                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|------|--------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 16.3 | Precautionary Statements | P261: Avoid breathing vapor.<br>P280: Wear protective gloves and eye protection<br>P305 + P351: If in eyes, rinse cautiously with water for several minutes.<br>P337 + P313: If eye irritation persists, get medical advice/attention.<br>P302 + P352: If on skin, wash with plenty of soap and water.<br>P333 + P313: If irritation or rash occurs, get medical advice / attention.<br>P410 + P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F. |
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|------|---------------------|----------------------------------------------------------------------------|
| 16.4 | Restrictions on use | Pulpdent products are to be sold to and used by dental professionals only. |
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|------|---------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 Pulpdent Corporation bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate. |
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| 16.6 | Sources of key data                                   | National Institute for Occupational Safety (NIOSH)<br>US Occupational Safety and Health Administration (OSHA)<br>Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH).<br>Guidance on the compilation of safety data sheets. Version 1.1; December 2011. European Chemicals Agency |
| 16.7 | Information which has been added, deleted or revised. | This Safety Data Sheet has been revised to meet the requirements of the GHS SDS format, 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.                                                                                                       |

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