


Safety Data SheetTrade Name: **PULPDENT ACTIVA™ PRESTO**

| 1.0 Commercial Product Name and Supplier | | | | | | | | | | | | | | | | | | |
|---|---|--|---------------------|------------------------|-------------------------|----------------|---|------|---------|---|------|-----------------|---|------|--------------------|---|------|--|
| 1.1 | Commercial product name / designation | ACTIVA™ PRESTO Light-cured Composite | | | | | | | | | | | | | | | | |
| 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 | <p>Pulpdent Corporation 80 Oakland Street, P.O. Box 780 Watertown, MA 02472 USA</p> <p>Telephone: 1 617 926-6666 Fax: 1 617 926-6262 Email: Pulpdent@pulpdent.com</p> | | | | | | | | | | | | | | | | |
| 1.4 | Emergency Telephone Number | 1-800-535-5053 (24 Hour / USA) | | | | | | | | | | | | | | | | |
| 1.5 | Authorized European Representative | <p>Advena Limited Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta</p> | | | | | | | | | | | | | | | | |
| | UK Responsible Person | <p>Advena Limited Pure Offices, Plato Close Warwick, CV34 6WE United Kingdom</p> | | | | | | | | | | | | | | | | |
| | CH Authorized Representative | <p>MedEnvoy Switzerland Gotthardstrasse 28, 6302 Zug, Switzerland</p> | | | | | | | | | | | | | | | | |
| 2.0 Hazards Identification | | | | | | | | | | | | | | | | | | |
| 2.1 | Classification | Irritant. | | | | | | | | | | | | | | | | |
| 2.1.1 | Classification according to Regulation (EC) No 1272/2008 [CLP] | <table border="1"> <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 per Directive 67/548/EEC | Irritant; Xi; R 36/37/38 – 43 (See SECTION 16 for full text of risk phrases) | | | | | | | | | | | | | | | | |
| 2.2 | GHS Label Elements | | | | | | | | | | | | | | | | | |
| | Hazard Pictograms | | | | | | | | | | | | | | | | | |
| |  | | | | | | | | | | | | | | | | | |
| | Signal Word: WARNING | | | | | | | | | | | | | | | | | |
| | Restricted to use by dental professional only. | | | | | | | | | | | | | | | | | |
| | Hazard Statements | | | | | | | | | | | | | | | | | |
| | 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. | | | | | | | | | | | | | | | | | |
| | Precautionary Statements | | | | | | | | | | | | | | | | | |
| | P261: Avoid breathing vapor. | | | | | | | | | | | | | | | | | |
| | P280: Wear protective gloves and eye protection | | | | | | | | | | | | | | | | | |
| | P305+P351: If in eyes, rinse cautiously with water for several minutes. | | | | | | | | | | | | | | | | | |

Safety Data SheetTrade Name: **PULPDENT ACTIVA™ PRESTO**

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.

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

3.0 Composition

3.1 Chemical characterization of the preparation: Light-cured, glass-filled resins.

3.2 Hazardous ingredients

| CAS Number | Name of the Ingredient | Concentration | Classification per 67/548/EEC | Classification per Regulation (EC) No.1272/2008 (CLP) |
|---------------------|---|---------------|---------------------------------|---|
| Proprietary mixture | Blend of diurethane and other methacrylate resins | 35.0% | Irritant; Xi R 36/37/38 - 43 | Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317 |
| 112945-52-5 | Silica, amorphous | 4.8% | Irritant; Xi, R 36/37/38 | Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 |

4.0 First Aid Measures

| | | |
|-----|----------------------------------|---|
| 4.1 | General Information | May be irritating to eyes, respiratory system, skin. Prolonged or repeated contact with resins may cause sensitization. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty. |
| 4.2 | Inhalation | Move to fresh air. If necessary, administer oxygen and/or artificial respiration and seek medical attention. |
| 4.3 | Skin Contact | Take off contaminated clothing. Wash skin thoroughly with soap and water for 15 minutes. |
| 4.4 | Eye Contact | Keep eyelids apart and flush with running water for 15+ minutes. Get medical attention. |
| 4.5 | Ingestion | Rinse mouth with water. Do not induce vomiting. Get immediate medical attention. May be irritating to mucous membranes. Never give anything by mouth to an unconscious person. |
| 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 may cause polymerization with rapid release of energy. |
| 5.4 | Special protective equipment for fire-fighters | A self-contained breathing apparatus should be worn by fire-fighters. |

Safety Data SheetTrade Name: **PULPDENT ACTIVA™ PRESTO**

| 6.0 Accidental Release Measures | | |
|--|--|--|
| 6.1 | Personal precautions. | Ventilate area. Wear safety glasses, gloves and lab coat. |
| 6.2 | Environmental precautions | Contain spilled material. Follow all government regulations. |
| 6.3 | Method for clean up | Absorb or wipe up spill with 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. Follow good hygiene practices. Remove applicator tip from syringe and recap immediately after use. Keep light-cured materials shaded from intense light sources. |
| 7.2 | Storage | Keep tightly capped. Store in original container at cool room temperature (<25°C). Avoid direct light, sources of ignition, extremes of temperature (>27°C/80°F, <5°C/40°F). 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. |
| 8.2.1.1 | Respiratory protection | Good general ventilation is sufficient to control any airborne vapors. |
| 8.2.1.2 | Hand protection | Usual surgical gloves will limit contact with uncured material. |
| 8.2.1.3 | Eye protection | Usual safety glasses. |
| 8.2.1.4 | Skin protection | Good personal hygiene and safety practices; 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. To the best of our knowledge, cured material is inert. Follow all government regulations. |
| 9.0 Physical and Chemical Properties | | |
| 9.1 | Characteristics | |
| 9.1.1 | Appearance /Color / Physical state | Paste in tooth shades |
| 9.1.2 | Odor | Faint, characteristic |
| 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 |

Safety Data SheetTrade Name: **PULPDENT ACTIVA™ PRESTO**

| | | |
|---------------------------------------|--|---|
| 9.2.8 | Specific gravity | 1.820 ± 0.02 g/ml |
| 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 | Not determined |
| 10.0 Stability and reactivity | | |
| 10.1 | Conditions to avoid | Temperature extremes (>27°C/80°F, <5°C/40°F), light. |
| 10.2 | Materials to avoid | Reducing and oxidizing agents, peroxides, amines. |
| 10.3 | Hazardous decomposition products | Under fire conditions, with amounts greater than in this product, hazardous polymerization may occur with heat buildup, release of carbon monoxide, carbon dioxide, oxides of nitrogen. |
| 10.4 | Further information | Polymerization will occur when light-cured material is exposed to direct light. |
| 11.0 Toxicological information | | |
| 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 of this material may cause eye and respiratory irritation. |
| 11.5 | Carcinogenicity, Mutagenicity, Reproductive Toxicity | None known. |
| 11.6 | Empirical data | None available. |
| 11.7 | Clinical experience | ACTIVA™ PRESTO is new to the market, but initial evaluations have been positive. There have been no reports of adverse events. |
| 12.0 Ecological Information | | |
| 12.1 | Ecotoxicity | To the best of our knowledge, polymerized material is inert. No other information is available. |
| 13.0 Disposal Considerations | | |
| 13.1 | Regulations | Polymerize before disposal. Follow all local and national government regulations in disposing material or contaminated packaging. |
| 14.0 Transport Information | | |
| 14.1 | Restrictions | None. Not regulated by IATA. |

Safety Data SheetTrade Name: **PULPDENT ACTIVA™ PRESTO**

| 15.0 Regulatory Information | | |
|------------------------------------|---|---|
| 15.1 | US FDA | Class II medical device |
| 15.2 | EU | Class IIa medical device |
| 15.3 | Health Canada | Class III medical device |
| 16.0 Other information | | |
| 16.1 | List of relevant R phrases | R36/37/38: Irritating to eyes, respiratory system and skin. R43: Sensitizing by skin contact |
| 16.2 | Hazard Statements | H319: Eye irritation. Hazard category 2. H335: Specific Target Organ Toxicity - Single exposure; hazard category. 3. Respiratory tract irritation. H315: Skin irritation. Hazard category 2. H317: Skin Sensitization. Hazard category 1. |
| 16.3 | Precautionary Statements | 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. P410+P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F. |
| 16.4 | Restrictions on use | Pulpdent products 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 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. |
| 16.6 | Sources of key data | National Institute for Occupational Safety (NIOSH) US Occupational Safety and Health Administration (OSHA) Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH). 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. |